EXHIBIT A

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Steamfitters Local Union No. 420 and the Class

STEAMFITTERS LOCAL UNION NO. 420, *individually and on behalf of all others similarly situated,*
14420 Townsend Road
Philadelphia, PA 19154

Plaintiff,

v.

MALLINCKRODT ARD, LLC,
***f/k/a* Mallinckrodt ARD, Inc.;**
***f/k/a* Questcor Pharmaceuticals, Inc.;**
1425 U.S. Route 206
Bedminster, NJ 07921

UNITED BIOSOURCE CORPORATION,
***now known as* UNITED BIOSOURCE LLC,**
***a wholly owned subsidiary of* UNITED BIOSOURCE HOLDINGS, INC.**
920 Harvest Drive
Blue Bell, PA 19422

Defendants.

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CIVIL ACTION NO. _____

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CIVIL CLASS ACTION COMPLAINT

Plaintiff, Steamfitters Local Union No. 420 ***("Local 420" or "Plaintiff"***), by and through its undersigned counsel, individually and on behalf of all other third-party payors ("TPPs") and their beneficiaries similarly situated, alleges as follows:

I. NATURE OF THE CASE

1. Steamfitters Local Union No. 420 brings this action on behalf of itself, its beneficiaries, and all other TPPs and their beneficiaries similarly situated, to challenge the unjust, unfair and deceptive marketing and sales scheme and conspiracy by Defendants, Mallinckrodt ARD LLC, formerly known as Mallinckrodt ARD, Inc., and, prior to that, formerly named Questcor Pharmaceuticals, Inc. (**"Questcor"**)(collectively **"Mallinckrodt"*)***, along with its named and unnamed co-conspirators as further described herein. Specifically, Plaintiff names United BioSource Corporation n/k/a United BioSource LLC (***"UBC"***) for its direct role in the scheme and conspiracy alleged.

2. Mallinckrodt manufactures, markets, distributes and sells H.P. Acthar Gel, NDC Nos. 63004-8710-01 and 63004-7731-01 (**"Acthar"**). Acthar is the only therapeutic ACTH product sold in the United States. Mallinckrodt is the sole provider of Acthar in the U.S.

3. Mallinckrodt acquired Acthar in July 2001, when Questcor purchased Acthar from Aventis Pharmaceutical Products Inc. for $100,000.

4. Acthar is a "specialty pharmaceutical". Unlike most prescription drugs, it is not sold in retail pharmacies, nor is it distributed through wholesalers to retail pharmacies. Instead, it is distributed only through "specialty pharmacy distributors" (**"SPDs"**) and "specialty pharmacy providers" (**"SPPs"**).

5. While there are dozens of SPDs and SPPs in America, one of the largest SPDs is

CuraScript, Inc., doing business as CuraScript SD, and Priority Healthcare Corp, also doing business as CuraScript SD (collectively, "**CuraScript**"). One of the largest SPPs is Accredo Health Group, Inc. ("**Accredo**"). Express Scripts, Inc. has owned both CuraScript and Accredo since 2004. Express Scripts also owned UBC, and its predecessor entity HealthBridge, form 2007 through the end of 2017.

6. In 2007, Mallinckrodt decided to embark on a self-described "new strategy" with respect to the distribution, pricing, marketing and sales of Acthar. The mastermind of this new strategy was Gregg LaPointe, a member of Questcor's Board of Directors at the time, who joined with Steve Cartt, Questcor's Chief Operating Officer, to convince another Board member, Don Bailey, that the strategy should be implemented, over the objections of the existing Questcor CEO and several Board members and executives.

7. The new strategy had three essential components to it. These three components comprise the schemes that underscore the RICO enterprises and unfair and deceptive acts and practices at issue in this case.

8. First, Mallinckrodt changed the way it distributed and sold Acthar (the "**Distribution Scheme**"). It limited the distribution of Acthar from multiple distribution outlets to just one, CuraScript, and engaged UBC to act as its exclusive "HUB" of operations controlling both the distribution and reimbursement of Acthar directly with patients and TPPs. (CuraScript and UBC were both subsidiaries of Express Scripts.) Mallinckrodt created this exclusive distribution arrangement to limit and control distribution and output of Acthar, and to raise the prices of Acthar to unconscionable levels. Mallinckrodt and UBC created the Acthar Support and Access Program ("ASAP") described below as the vehicle to effectuate their Distribution Scheme.

9. While this conduct constitutes antitrust, and is the subject of a separate federal class action lawsuit pending in Rockford, Illinois[1], it is also the subject of separate *qui tam* lawsuits brought in this Court by former employees of Mallinckrodt, in which the federal government has intervened. *See U.S. ex. Rel. Charles Strunck and Lisa Pratta v. Mallinckrodt ARD, Inc., et al.* 2:12-cv-00175-BMS (E.D.Pa.) at Document No. 40 ("*Strunck & Pratta Complaint*"); *U.S. ex. Rel. Scott Clark v. Questcor Pharmaceuticals, Inc.*, 2:13-cv-01776-BMS (E.D.Pa.) at Document 1 ("*Clark Complaint*").

10. Local 420 brings no overlapping claims against Mallinckrodt or UBC in this lawsuit for any alleged antitrust violations. Instead, it sues on behalf of itself and all similarly situated TPPs of Acthar for consumer fraud, RICO violations and other common law claims arising out of the unique distribution, pricing, marketing and sales schemes alleged herein, arising out of the unique claims alleged by several former employees of Mallinckrodt. The details of the conduct underlying these claims were only first revealed to Plaintiff and the Class in April 2019 when the *Strunck and Pratta Complaint* was unsealed by this Court.

11. Second, throughout the relevant time period, since August 2007 through the present, Mallinckrodt has willfully manipulated and inflated the prices paid by TPPs for Acthar, causing TPPs like Local 420 to substantially overpay for a drug with very limited uses and benefits and an unknown method of action (the "**Pricing Scheme**"). Specifically, after limiting Acthar distribution by the Distribution Scheme, in August 2007, Mallinckrodt agreed with CuraScript and UBC to raise the average wholesale prices ("**AWPs**") paid for Acthar by TPPs like Local 420 from $2,062.79 per vial to $29,086.25, a more than 1,300% increase in the cost of Acthar in the span of one month. Such a price increase is both unprecedented and

[1] *See City of Rockford v. Mallinckrodt ARD, Inc., et. al.*, Case No. 17-cv-50107 (N.D.Ill.) (hereinafter the "***Rockford* case**").

unconscionable, especially for a more than 65-year old drug. Mallinckrodt, Curascript and UBC have continued to raise the AWPs for Acthar each year, sometimes by double-digit percentages, such that now a drug that once cost $40.00 costs patients and third-party payors over $43,000.00. The only way Mallinckrodt has been able to get TPPs to pay such high prices for Acthar was through the fraudulent schemes alleged herein. But for such schemes, TPPs like Local 420 would not have paid what they did for Acthar.

12. Third, Mallinckrodt and UBC devised a marketing and sales scheme designed to ensure that Acthar was reimbursed by TPPs at the new, inflated AWPs, without substantial backlash from patients and payors (the "**Marketing Scheme**"). Fearing an uproar of complaints from patients, patient support groups, private TPPs and the federal government for their unjustified distribution limitations and price increases, and in order to circumvent TPP cost containment mechanisms for high-priced specialty drugs, Mallinckrodt devised a multi-faceted scheme and RICO enterprise to bribe doctors in order to induce them to prescribe Acthar over other available treatments. The scheme involved cultivating key opinion leaders (or "KOLs") from around the country to serve as the company's "spokes-doctors" in promoting prescriptions of Acthar for unapproved uses and doses. The scheme also sought to remove patient complaints about high co-pays on Acthar by funneling tens of millions of dollars to UBC to run a so-called "patient assistance program" or "PAP" designed to ensure that private TPPs paid the bulk of the costs of Acthar.

13. On April 30, 2019, it was revealed publically for the first time by CNN[2] that two whistleblowers, both former pharmaceutical sales representatives for Mallinckrodt, had sued the company years before for a "multi-tiered strategy" to boost sales by bribing doctors to prescribe

[2] https://www.cnn.com/2019/04/30/health/mallinckrodt-whistleblower-lawsuit-acthar/index.html

the high-priced Acthar to their patients. As described more fully in the *Strunck & Pratta Complaint*, Mallinckrodt's scheme involved "using valuable incentives, rewards and other forms of renumeration to induce health care providers to promote and prescribe H.P. Acthar in lieu of less expensive therapies that are equally more effective…". *Strunck & Pratta* Cmplt. at ¶ 3(i). According to Strunck and Pratta, there is a pervasive culture at Mallinckrodt designed to sell Acthar at all costs.

14. Separately, a different whistleblower sued Mallinckrodt in this Court on April 4, 2013, alleging a different aspect of Mallinckrodt's scheme to sell Acthar at high prices. In a case unsealed as part of the government's filing of a consolidated, amended pleading, former employee Scott Clark alleges that "Mallinckrodt designed supposed 'patient assistance' funds that paid copays for Acthar only and then funded them through 'donations', knowing its money would be used on Acthar copays to the exclusion of other drugs." *See* United States' Complaint in Intervention, Dkt No. 2:13-cv-01776-BMS (E.D.Pa.) (BMS) at Document No. 57 ("***U.S. Complaint***") at ¶ 5. Such conduct is unlawful.

15. As the federal government has alleged:

> "Mallinckrodt knew that the cost of Acthar would make it difficult to sell because there were cheaper, effective competitor drugs available to treat certain of its approved uses, namely acute exacerbations in multiple sclerosis, lupus and rheumatoid arthritis. Mallinckrodt intended to overcome this difficulty and did so by making the drug 'free' to patients by subsidizing their Medicare [and private] copayments. By doing so, Mallinckrodt could maintain the high price of Acthar to maximize its own sales revenues, but minimize the risk that the drug's high price would impede doctors and patients from using it."

Id. at ¶ 4 (brackets added).

16. Accordingly, in conjunction with limiting Acthar distribution and raising the prices for Acthar in 2007, as part of the Distribution and Pricing Schemes, Mallinckrodt also

embarked on a Marketing Scheme designed to incentivize sales of Acthar at the new high prices. Patients and TPPs had no choice but to pay the high prices charged by Mallinckrodt and UBC, Mallinckrodt's exclusive agent and "HUB".

17. Mallinckrodt vastly expanded its direct-to-consumer selling of Acthar by expanding its sales force, including creating a team of "medical science liaisons" or "MSLs". The MSLs were highly trained specialists in the Acthar treatments who worked with other Mallinckrodt sales representatives to create a network of KOLs. These KOLs were leading specialists in their respective medical fields whom Mallinckrodt identified as being potentially influential on other doctors. These KOLs were paid handsomely to join with Mallinckrodt's MSLs and sales representatives as "spokes-doctors", promoting Acthar to other medical providers and delivering Mallinckrodt's false, misleading and deceptive promotional messages about the safety, efficacy and value of Acthar in relation to other cheaper, safer, and equally or more effective treatments. As a result, thousands of new patients have been prescribed Acthar for unapproved uses and doses in the treatment of diseases in neurology, nephrology and rheumatology, among others. And TPPs have been force to pay the exorbitant prices charged by Defendants.

18. Local 420, other TPPs who have sued in state courts,[3] and the Class of TPPs and their beneficiaries were harmed by Mallinckrodt's conduct. Specifically, in 2018, Local 420 paid for Acthar at the inflated prices charged by Defendants as a result of the Distribution, Pricing, and Marketing Schemes alleged. To date, Local 420 has paid $152,798.92 for Acthar, more than it otherwise would have paid in the absence of Mallinckrodt's scheme and conspiracy.

[3] One such TPP is the International Union of Operating Engineers Local 542 ("IUOE Local 542") based in Fort Washington, Pennsylvania. IUOE Local 542 sued Mallinckrodt and UBC in the Court of Common Pleas for Montgomery County, Pennsylvania in May 2018.

19. Local 420 brings this lawsuit on behalf of itself and a Class of all similarly-situated TPPs and their beneficiaries who paid for Acthar at prices based on the inflated AWP prices set by Mallinckrodt during the relevant time period between August 2007 and the present. Because some of the TPPs in the Class have already sued Mallinckrodt in state courts on their individual claims, Local 420 seeks to obtain declaratory and injunctive relief in this Court on behalf of a nationwide Class of all TPPs, in order to have the conduct of Defendants declared unlawful and enjoined, for the benefit of all affected TPPs and their beneficiaries. Local 420 also seeks to recover money damages for overpayments based on inflated AWP prices for Acthar, pursuant to federal RICO and the consumer protection laws of Pennsylvania and other states, as well as the common law of Pennsylvania and other states. Finally, Plaintiff seeks punitive damages for the Defendants' willful, outrageous and reckless conduct.

II. JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because Local 420 and members of the Class are diverse from the Defendants and over two-thirds of the Class is situated outside of Pennsylvania. Due to the exorbitant prices charged by Defendants for Acthar to the Class – currently over $43,000.00 per prescription for a drug that used to cost a little more than $2,000 -- the aggregate amount in controversy far exceeds $5,000,000 for the Class.

21. This Court has personal jurisdiction over Plaintiff because it is located in Pennsylvania and it reimbursed for Acthar and other drugs in Pennsylvania.

22. This Court has jurisdiction over the Defendants because they are present and/or conduct substantial business in Pennsylvania, have registered to conduct business here, have had systematic and continuous contacts with Pennsylvania, and/or have agents and representatives

that can be found in Pennsylvania. The Court also has jurisdiction over multiple, unnamed co-conspirators who assisted Mallinckrodt in carrying out its scheme, including sales representatives, MSLs, and KOLs located in Pennsylvania as described herein.

23. The Court also has jurisdiction over the Defendants because they have had sufficient minimum contacts with and/or have purposefully availed themselves of the laws and markets of Pennsylvania through, among other things, their distribution, marketing and sales of Acthar to Local 420 and other residents of Pennsylvania.

24. Venue is proper in this District because Local 420 is situated in this District, and the Defendants transact business in this District. Venue is also proper because a substantial part of the events giving rise to Local 420's claims occurred in this District. Defendants also engaged in substantial conduct relevant to the claims of Local 420 and the Class, and caused harm to members of the Class in this District. Venue is also proper pursuant to 28 U.S.C. §1391.

25. Acthar is sold in both interstate and intrastate commerce, and the unlawful activities alleged in this Complaint have occurred in Pennsylvania and this District.

III. THE PARTIES

A. PLAINTIFF

26. Local 420 is a Taft-Hartley union fund providing health and welfare benefits to its members and their families. Local 420 has a business address at 14420 Townsend Road, Philadelphia, Pennsylvania 19154, which is situated in Philadelphia County, Pennsylvania.

27. Local 420 has represented the interests of working men and women in eastern Pennsylvania since 1935, including heavy equipment operators in the building and construction industry, along with C & D-Branch Division members who are employed at quarries, landfills, equipment dealers, shipyards, breweries, manufacturing plants, airports, bridges, and public

works.

28. Local 420 provides healthcare benefits to its employees through Independence Blue Cross ("IBC"). While IBC coordinates Local 420's prescription drug benefits, including specialty drugs like Acthar, through Future Scripts, a pharmacy benefits manager ("PBM"), Local 420 is self-funded, meaning that Local 420 and its beneficiaries pay the full costs of drugs like Acthar.

29. The spouse of one such member of Local 420 has a medical condition, a rheumatic disorder, for which Acthar was prescribed for treatment. As described more fully herein, rheumatic conditions became a target of Defendant's marketing and sales scheme to promote the sale of Acthar at artificially inflated prices. She received four separate prescriptions of Acthar in early 2018. Local 420 then paid for these administrations of Acthar at a net cost of $38,199.73 for each such prescription. The net cost was based upon the inflated AWP of Acthar as set by Mallinckrodt.

30. The sum total of the 4 prescriptions paid for by Local 420 was $152,798.92. The member/beneficiary was required to pay a co-pay of $70.00 for each prescription, for a total of $280.00. As a result, Local 420 has incurred a financial harm due to the Defendants' conduct stated herein.

B. DEFENDANTS

31. Defendant Mallinckrodt ARD LLC ("Mallinckrodt") has its principal place of business at 1425 U.S. Route 206, Bedminster, New Jersey 07921. Mallinckrodt ARD LLC was previously named Mallinckrodt ARD, Inc., and before that was named Questcor Pharmaceuticals, Inc. ("Questcor").

32. Mallinckrodt ARD LLC is an indirect wholly-owned subsidiary of Mallinckrodt

plc, an Irish public limited company, with its corporate headquarters in Staines-upon-Thames, United Kingdom.

33. On April 4, 2014, Mallinckrodt plc entered into an Agreement and Plan of Merger with Questcor and effectuated the acquisition of Questcor on August 14, 2014 for approximately $5.9 billion.

34. Following the merger, Questcor continued to market and sell Acthar, until changing its name to Mallinckrodt ARD Inc. on July 27, 2015.

35. On January 26, 2019, Mallinckrodt ARD, Inc. converted to Mallinckrodt ARD LLC and continues to market Acthar under that name today.

36. Defendant United BioSource Corporation n/k/a United BioSource LLC ("UBC") is a Delaware corporation with its corporate headquarters at 920 Harvest Drive, Blue Bell, Pennsylvania 19422. UBC has been a wholly-owned subsidiary of Express Scripts from 2007, when it was known as HealthBridge. In 2012, UBC was acquired by Express Scripts as part of the Medco merger, and HealthBridge was renamed UBC. In November 2017, Express Scripts announced that it sold UBC to Avista Capital Partners, a private equity firm.

37. UBC is a wholly owned subsidiary of United BioSource Holdings, Inc., the interests of which are held by and through various privately held intermediary entities, which are ultimately owned by private investment funds sponsored by and/or affiliated with Avista Capital Partners and as-yet-unknown individuals associated with Avista Capital Partners.

38. UBC is Mallinckrodt's exclusive "agent" designated to operate the Acthar Support and Access Program ("ASAP"), a program put in place in 2007 as part of the "new strategy" to manage the Acthar's exclusive distribution and sales directly to patients. UBC is specifically identified as Mallinckrodt's agent on the Acthar Start Form, which every patient and

health care provider ("HCP") is required to fill out and sign prior to receiving Acthar. *See* 2018 Acthar Start Form at **Exhibit "A" hereto.**

39. UBC operates as the Mallinckrodt's "HUB" of operations for Acthar distribution and payment, coordinating all aspects of the scheme and conspiracy, from the initial identification of patients, insurance and payment verification, through to payment by TPPs, like Local 420 and the Class.

40. The corporate Defendants' acts alleged in this Complaint to have been done by each of the Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.

IV. FACTUAL BACKGROUND

A. ACTHAR DEVELOPMENT AND LIMITED APPROVAL BY THE FDA

41. Acthar was approved by the FDA on April 29, 1952 for over 50 conditions, ranging from alcoholism, poison ivy, and radiation sickness to nephrotic syndrome. Over time, as discussed below, with additional evidence-based requirements for prescription drugs, the list was winnowed by the FDA to the fewer, present-day 19 indications.

42. Acthar is adrenocorticotropic hormone ("ACTH"), which causes the body to produce cortisone and other steroid hormones. Two Mayo Clinic researchers, Drs. Philip Hench and Edward Kendall, developed the treatment, which won them the Nobel Prize for medicine at the time it was developed.

43. Acthar was developed by Armour Pharmaceutical Company. As described by the Seventh Circuit in *Armour & Co. v. Wilson & Co.*, 274 F.2d 143, 145-46 (7th Cir. 1960):

> In a human being, . . . (ACTH) appears in the anterior lobe of the pituitary gland located at the base of the brain. When the human

> body is under stress or attacked by certain diseases, control centers in the brain excite the pituitary, and the pituitary secretes ACTH. In the blood stream the ACTH thus secreted is carried to the adrenal glands situated in the human body above the kidneys. As the ACTH hits the outer wall of the adrenal glands, it stimulates the adrenals to produce a set of chemical substances such as steroids, including the hormones, cortisone and hydrocortisone.
>
> The cortisone hormones then act in the tissues of the body to suppress inflammations and allergic reactions. ACTH thus is used to relieve such conditions as rheumatoid arthritis and allergies. ACTsH does not, itself, directly attack disease. However, it stimulates the adrenals which produce more than twenty-eight steroids, and these hormones attack the diseased tissues. When the human body itself does not supply sufficient ACTH, pharmaceutical ACTH can fill the gap.

44. In layman's terms, ACTH is a hormone released by the brain that triggers the adrenal glands to make cortisol, which is the body's equivalent of prednisone, a steroid. ACTH works by inducing a patient's adrenal glands to release cortisol, thereby replicating the effect of taking prednisone. Because of this, ACTH has risks and benefits similar to those of prednisone.

1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed.

45. Under FDCA 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

46. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(l)(A).

47. Under the nation's food and drug laws, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. 21 U.S.C. §321. The law requires that "adequate and well controlled investigations" be used to demonstrate a drug's safety and effectiveness. 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. 21 U.S.C. § 355(d)(5). The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. 21 U.S.C. § 355(d)(1) & (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. 37 Fed. Reg. 16,503 (1972). They are "unapproved" uses.

48. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment. 21 C.F.R. § 314.26.

49. The FDA also requires the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. In order to address this requirement, the FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 Guidance to the Industry, "it has been FDA's position that Congress generally intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." *See* U.S. Department

of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products, May 1998. *See also, Final Decision on Benylin*, 44 FR 51512, 518 (Aug. 31, 1979).

50. The FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate report suggested that the phrase "adequate and well-controlled investigations" was designed not only to describe the quality of the required data but also the "quantum" of required evidence. *See* S. Rep. No. 1744, Part 2, 87th Cong.2d Sess. 6 (1962).

51. In Section 115(a) of the Medicare Modernization Act, Congress amended section 505(d) of the Act to make it clear that the FDA may consider "data from one adequate and well-controlled clinical investigation and confirmatory evidence" to constitute substantial evidence if the FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed FDA's interpretation of the statutory requirements for approval and acknowledged the FDA's position that there has been substantial progress in the science of drug development resulting in higher quality clinical trial data.

52. Cases in which the FDA has approved a drug on the basis of one clinical trial plus, confirmatory evidence are rare. They include instances of large, independently conducted multi-center trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug

development phases, but are exceptionally unlikely to qualify as "adequate and well-controlled" clinical trials needed to support FDA approval.

53. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. 21 C.F.R. § 201.57(3).

2. FDA Regulations Prohibit Off Label Marketing Through False and Misleading Statements About a Drug's Use or Benefits.

54. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 852; 21 C.F.R. § 314.81. Drug labels, including all marketing and promotional materials relating to the drug, may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C.§§ 331; 352. Illegal "misbranding" can result in criminal penalties. 21 U.S.C. § 333.

55. Drug companies such as Mallinckrodt must submit specimens of mailing pieces and any other labeling or advertising devised or used for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA-2253. This constitutes a specific and material representation that all promotional items are being disclosed and provided to the FDA. Moreover, it constitutes an implied representation that the promotion and marketing that is being done through verbal communications, including inter alia, any drug company's speech or "advertisement" for the product, which are also subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, is consistent and m line with any written communications being submitted to FDA.

56. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict scientific procedures) and they may not be false, deceptive or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

57. A drug company that wishes to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA") 21 U.S.C.§§ 360aaa(b), (c); *see also* 21 C.F.R.§ 814.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301, *et seq*. A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

58. The term "off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population, *e.g.*, treating a child when the drug is approved to treat adults.

59. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians are supposed to depend on the patient-specific evidence they have available to them. This should include the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on or off-label use, physicians also sometimes rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Regrettably, much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug company sponsored continuing medical education ("CME") courses and speaker programs, and drug company sponsored clinical trials.

60. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than

labeling) that originates from the same source as the product and that is intended to supplement or explain the product."

61. Any drug company's speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, as well as the FDA's "fair balance" requirement, described below. While a drug company may be entitled to certain First Amendment protection for truthful speech, *see U.S. v. Caronia*, 703 F.3d 149 (2d. Cir. 2012), off-label promotion that is false or misleading is not entitled to First Amendment protection. *Caronia*, 703 F.3d at 166 n. 10. *See Cent. Hudson*, 447 U.S. at 566, 100 S. Ct. 2343. Under 21 U.S.C. § 331(a), a defendant may be prosecuted for untruthfully promoting the off-label use of an FDA approved drug, *e.g.*, making false or misleading statements about a drug.

62. Section 202.1(e)(6)(xi) provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." *See also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id*. at § 331(a) (prohibiting distribution of a misbranded drug); *id*. at § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

63. The FDA regulations that fall under the general rubric of 21 C.F.R. 202.1(e)(6), *et seq*. ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law. 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6).

64. Thus, companies like Mallinckrodt may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safer or more efficacious than

competitor drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by government programs, including Medicare and Medicaid.

65. The regulations prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." 21 C.F.R. 202.1(e)(6)(iv).

66. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use. 21 C.F.R. 202.1(e)(5), *et seq*. A company violates this regulation if it presents "false or misleading" information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id*.

67. Section 202.1(1)(2) broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug.

68. Section 201.56 requires labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibits "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness."

69. The FDA has interpreted oral communications as falling under the umbrella of "labeling."

70. Section 99.101, *et seq*. lays out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer reviewed article that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound" 21 C.F.R. 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. 21 C.F.R. 99.101(b)(2).

71. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. 99.101(a)(4).

72. Additionally, off-label information may be disseminated only in response to an "unsolicited request from a healthcare practitioner." 21 U.S.C. § 360aaa 6. In any other circumstance, a manufacturer may disseminate information concerning off-label use only after it has submitted an application to the FDA seeking approval of the drug for the off-label use, has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false or misleading. 21 U.S.C. §§ 360aaa (b) & (c); 360aaa 1.

73. The FDA does not generally regulate the exchange of scientific information, but when such information is provided by or on behalf of a drug company regarding one of the company's products, the information may be subject to the labeling and advertising provisions of the law and regulations. For example, while information provided at continuing medical education programs (such as medical conferences and professional gatherings intended to enhance physicians' knowledge and enable them to meet certain practice requirements) generally is not subject to FDA regulation, it will be subject to FDA regulation if the program has been funded and substantially influenced by a drug company.

74. In sum, the off label regulatory regime of the federal government protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. The prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

3. The FDA has limited ability to regulate drug company marketing and promotion.

75. The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off label uses. *See* Statement by Janet Woodcock, M D. (Director Center for Drug Evaluation and Research, FDA) Before the Senate Special Committee on Aging (July 22, 2003).

76. DDMAC's effectiveness in regulating off label promotion is limited. In 2003, the entire staff consisted of forty members, with twenty-five reviewers responsible for reviewing all drug advertisements and promotional materials. Moreover, drug materials do not have to be pre-

approved. FDA review of promotional materials occurs, if at all, only after the materials already have appeared in public. *See* Woodcock Statement, *supra*. Upon finding a violation, DDMAC generally requests, but does not require, the company to stop using the promotional materials. *Id.* Sponsors occasionally are required to publicly correct product misimpressions created by false, misleading, or unbalanced materials. *Id.*

77. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer, and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.

78. The FDA's ineffectiveness in policing off label promotion was confirmed in a July 28, 2008 U.S. General Accountability Office Report, which found that the FDA took an average of seven (7) months to issue letters in response to off-label promotions. *See* Drugs: FDA Oversight of the Promotion of Drugs for Off-Label Uses (GAO 08-835), http:1www.gao.gov/new.items/d08835.pdf. Among the Report's findings: (i) FDA does not have separate oversight activities to specifically capture off-label promotion; (ii) FDA is unable to review all promotional submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health; (iii) FDA is hampered by the lack of a system that consistently tracks the receipt and review of submitted materials; (iv) FDA conducts limited monitoring and surveillance to identify violations that would not be identified through its review of submitted materials, for instance, discussions between doctors and sales representatives; (v) during calendar years 2003 through

2007, FDA issued 42 regulatory letters in response to off-label promotions requesting drug companies to stop dissemination of violative promotions.

4. Mallinckrodt's false and misleading marketing of Acthar for a "mode of action" that is unknown, and for uses and doses that are not approved by the FDA.

79. According to the "Pre-Decisional Agency Memo" issued September 27, 2010 by the DDMAC for Acthar, NDA 022432 (**"DDMAC Memo"**), the formulation of ACTH now known as H. P. Acthar Gel (Repository Injection), which is known generically as corticotropin, was originally approved by the FDA *prior to* the 1962 Kefauver-Harris Amendment to the Federal Food, Drug And Cosmetics Act of 1962 ("FDCA"), which introduced the requirement of "substantial evidence" of two adequate and well controlled studies. ***See*** **DDMAC Memo attached hereto at Exhibit "B" hereto.**

80. In its 2010 assessment of Acthar, the DDMAC observed:

> At the time of the original approval drug manufacturers only had to show the drug was safe for use in humans. The original data included case reports from a few physicians describing patients with conditions originally treated with Acthar powder that were transferred to treatment with Acthar Gel and gave dosing guidance for treatment of these individual conditions. A few patients had improvements in hematology data and improvement in symptoms (decreased diarrhea, improved appetite, sense of well-being, etc.) reported to support the efficacy of treatment.
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> ***
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> **These data would be grossly inadequate to support approval of a new drug or new indications by the Agency under current standards requiring evidence from adequate and well-controlled clinical trials**.

DDMAC Memo at 2-3 at Exhibit "B" (emphasis supplied).

81. Remarkably in 2017, Mallinckrodt falsely stated that when the FDA reviewed Acthar's label in 2010, it "determined there was sufficient scientific evidence and clinical evidence to support the 19 indications now in the current label." **Mallinckrodt Statement on**

H.P. Acthar Gel (Repository Corticotropin Injection) Update, dated June 22, 2017, attached hereto as Exhibit "C" ("**Mallinckrodt 2017 Statement**"). The Mallinckrodt 2017 Statement claimed to "[t]o address the false and misleading information about Mallinckrodt Pharmaceuticals and its product H.P. Acthar Gel," when in point-of-fact, it did the opposite: it presented a demonstrably false and misleading picture about Acthar's safety (including the increasing incidence of adverse events), efficacy and approval by the FDA.

82. In fact, directly contradicting Mallinckrodt's false claims about the alleged "sufficiency of scientific evidence," the Director of the Division of Neurology Products, Dr Russell Katz, wrote:

> The **sponsor [Mallinckrodt] had not conducted any trials of its own**, and, in brief, we determined that the sponsor should attempt to obtain primary data for several trials published in the archival literature that, potentially, could provide substantial evidence of effectiveness for Acthar Gel for IS.
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> * * *
>
> The data that the sponsor has provided differ considerably from that typically submitted in an NDA. As noted earlier, **none of the studies were commissioned or conducted by the sponsor, and detailed protocols, and, in particular, detailed statistical plans for the analyses of these studies, did not exist.**

April 5, 2010 Memorandum from Russell Katz, M.D. at 1, 9 (available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s0900SumR.pdf) (emphasis supplied).

83. Mallinckrodt continued to press its false and misleading narrative about the FDA's purported "approv[al] for 19 indications … following a full label review by the Agency in 2010" into 2018, when Local 420 began to pay for Acthar. *See* **Mallinckrodt Statement, "Facts About H.P. Acthar Gel, H.P. Acthar Gel Value to Patients" dated June 29, 2018 attached hereto as Exhibit "D" ("Mallinckrodt 2018 Statement")**.

5. Acthar's DESI review and narrowing of approved indications due to a lack of proven efficacy and safety.

84. Despite published reports that Acthar was somehow "grandfathered" by the FDA, in truth Acthar was subjected to a Drug Efficacy Study Implementation (DESI) review in the early 1970s. The FDA has always required proof of safety and efficacy for the approval of prescription drugs.

85. At the time of the 1962 amendments to the FDCA, there were thousands of drugs on the market whose effectiveness was suspect or altogether unknown. The amendments thus required the FDA to ***withdraw*** prior approval of a drug if it found: "on the basis of new information before [it] with respect to such drug, evaluated together with the evidence available to [it] when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof." *FDCA, 21 U.S.C. § 355(e).*

86. Acthar was thus subjected to a DESI review in 1971, and was **found to be effective only for a narrow subset of indicated uses**. The 1971 report titled "Corticotropin for Parenteral Use", Federal Register, Vol. 36, No. 152 (Aug. 6, 1971) at 14509-14510, found Acthar "lacking substantial evidence of effectiveness" for its "recommended use" in over 30 of its originally approved indications. With respect to certain of the remaining indications, the FDA found Acthar "probably effective"; for others, the FDA found "these drugs are regarded as possibly effective for their labeled indications." *Id*. at 14510.

87. In 1977, the FDA issued a "Follow Up Notice and Opportunity for Hearing", Federal Register, Vol. 42, No. 40 (March 1, 1977) at 11891-11892, in which it reported:

> [on] August 6, 1971, the [FDA] announced its conclusions that the drug products described below [including Acthar] are effective, probably effective, possibly effective, and lacking substantial evidence of

> effectiveness for their various labeled indications. The notice provided an opportunity for a hearing for the indications concluded at the time to lack substantial evidence of effectiveness. **No data in support of any of the less-than-effective indications were submitted. All such indications are now reclassified to lacking substantial evidence of effectiveness. …No person requested a hearing concerning them, and they are no longer allowable in the labeling**.
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> ***
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> **The drugs now lack substantial evidence of effectiveness for the indications evaluated as probably and possibly effective for the indications evaluated as probably and possibly effective in the August 6, 1971 notice**.

Id. (brackets added)(emphasis supplied).

88. As a result, Acthar was left with about 19 narrow indications. For instance, in the area of "rheumatic disorders", the disease for which Acthar was prescribed for Local 420's beneficiary, Acthar was approved only "as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in … rheumatoid arthritis". *Id*. at 11892 (parenthetical in original).

89. All other indications had been "reclassified to lacking substantial evidence of effectiveness" by the FDA. Nevertheless, Mallinckrodt has continued to tout Acthar's original approval in 1952 for "over 50 indications" in an effort to convince physicians, patients and TPPs that Acthar is widely approved to treat array of diseases, as opposed to just the 19 narrow indications for which it is actually approved. *See* listing of approved conditions below.

90. By the 1960s, Acthar was essentially a generic drug. Injectable ACTH medications faced a variety of competing products. *See Armour & Co. v. Wilson & Co.*, 274 F.2d at 145 ("Both Armour and Wilson manufacture and sell gelatin-ACTH preparations . . . . Gelatin-ACTH now constitutes more than 80% [o]f all forms of ACTH products sold by Armour and Wilson. Other companies . . . produce similar products").

91. For the majority of the Acthar's drug lifespan, however, generic corticosteroids, such as prednisone, effectively treated the majority of the indications for which Acthar was approved. That factor tended to limit the market for Acthar to treating infantile spasms ("IS") which was originally an "off-label" indication. Consequently, because of the limited, off-label market for Acthar, by 2001, the drug was priced at $40 per vial and accounted for less than a million dollars of revenue for Aventis, the then-owner.

92. Because prednisone is equally efficacious as Acthar, it has the same risks and benefits as Acthar, but at a far cheaper price. According to GoodRx.com, prednisone is available at leading retail pharmacies for little more than $4 (with coupons), including Walmart, Target, CVS, Walgreens and Giant.

93. Despite this, Mallinckrodt has continually marketed Acthar as the new and improved prednisone, but without any support through head-to-head studies with prednisone. While prednisone has been proven to be safe and effective for the vast majority of indications on Acthar's label, there is no data to support Mallinckrodt's claims that Acthar is equally or more efficacious than prednisone, or other corticosteroids, so as to warrant even the same price as prednisone, let alone the exorbitant price of Acthar.

94. The same is true of Solu-Medrol (methylprednisone), a synthetic corticosteroid used to treat some of the same conditions for which Mallinckrodt promotes Acthar. Specifically, Solu-Medrol is given to people with multiple sclerosis ("MS") to shorten relapses. The cost of Solu-Medrol is around the same price as what Acthar used to cost, before Mallinckrodt acquired the product in 2001.

95. To try to deflect attention from the stark price differences between Acthar and generic prednisone, Mallinckrodt has engaged a small army of dedicated, highly-paid spokes-

doctors as KOLs to work with Mallinckrodt MSLs and its large sales force to promote sales of Acthar to the KOLs' peers. These KOLs work with Mallinckrodt and UBC to circumvent and bypass protections and controls imposed by TPPs to control and limit their expenditures on high-priced specialty drugs, like Acthar.

96. One major control utilized by payors is a "prior authorization" ("PA") process whereby a prescription for high-priced specialty medication like Acthar must be reviewed and authorized *before* the script written by the doctor is filled and charged to the TPP. However, Mallinckrodt and UBC have systematically circumvented such controls by their insistence that all patients and providers signing the blanket consents included on the Acthar Start Form at **Exhibit "A" hereto**, put in place in 2007 as part of the "new strategy". All such forms are faxed to UBC and processed through the "HUB" as described below, ensuring that unapproved uses and doses, like those prescribed to the beneficiaries of Local 420, IUOE Local 542, and other TPPs in the Class, are paid for at Mallinckrodt's inflated AWP.

6. Acthar's approved label indications.

97. As stated above, the FDA has approved Acthar for multiple, but limited, indications. These narrow indications, as set forth in the FDA-approved label, are:

a. As monotherapy for the treatment of infantile spasms ("**IS**") in infants and children under two years of age;

b. For the treatment of acute exacerbations of Multiple Sclerosis ("**MS**") in adults;

c. As adjunctive therapy for short term administration (to tide the patient over an acute episode or exacerbation) in the following Rheumatic Disorders: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis (collectively, "**RA**");

d. During an exacerbation or as maintenance therapy in selected cases of the following Collagen Diseases: systemic lupus, erythematosus, systemic dermatomyositis (polymyositis)(collectively, "**SLE**");

e. For the following Dermatologic Diseases: Severe erythema multiform and Stevens-Johnson syndrome;

f. For serum sickness;

g. For symptomatic sarcoidosis;

h. To induce a diuresis or a remission of proteinuria in the nephrotic syndrome ("**NS**") without uremia of the idiopathic type or that due to lupus erythematosus.

98. Despite these many, narrow indications, substantially all of Mallinckrodt's sales have been generated from just five of these indications: (1) IS, (2) MS, (3) SLE, (4) NS, and (5) RA.

7. Multiple Sclerosis (MS), Systemic Lupus Erythematosus (SLE), Nephrology Syndrome (NS) and Rheumatoid Arthritis (RA).

a. Multiple Sclerosis

99. Multiple sclerosis ("MS") is a central nervous system disease in which the body's immune system attacks the body's myelin nerve cell coating. MS can cause a variety of symptoms, which can increase in severity periodically.

100. MS "relapses," "acute exacerbations," or "flares" (collectively "MS exacerbations") are temporary periods of increased disease activity in an MS patient, manifested by the worsening of existing MS symptoms or the onset of other MS symptoms. MS exacerbations are not a separate disease from MS.

101. The FDA has approved several medications for the long-term treatment of MS patients, including medications to slow the accumulation of physical disability from the disease or to decrease the frequency of acute exacerbations. These medications are sometimes referred

to as MS "disease modifying" drugs or therapies. Acthar is not a "disease modifying" drug or therapy for MS.

102. The FDA also has approved drugs for treatment of MS exacerbations, such as Acthar. A standard treatment for MS exacerbations includes administering methylprednisolone, a steroid, which can be administered intravenously ("IVMP") or orally. One such treatment is Solu-Medrol. Both IVMP and oral methylprednisolone are available in several brand name or generic forms. The drugs are significantly less expensive than Acthar. Depending on the pharmacy from which it is obtained, generic methylprednisolone can be had for as little as $34 per gram, without coupon.

b. Systemic Lupus Erythematosus

103. Systemic lupus erythematosus ("SLE") is an autoimmune disease in which the body's immune system targets its own healthy cells. Lupus can damage the kidneys, brain, skin, joints, or other areas of the body.

104. SLE patients can experience "flares" or "exacerbations' (collectively "SLE exacerbations"), which are periods of increased disease activity and are characterized by worsening SLE symptoms.

105. SLE exacerbations are not a separate disease from SLE.

106. A standard treatment for SLE exacerbations includes the administration of steroids, which can be available in brand name or generic forms. The drugs are significantly less expensive than Acthar.

c. Nephrology Syndrome

107. Nephrology syndrome ("NS") is a kidney disease that causes one's body to excrete too much protein in the urine. NS is usually caused by damage to the clusters of small blood vessels in one's kidneys that filter waste and excess water from the blood.

108. A standard treatment for NS includes the administration of steroids, which can be available in brand name or general forms. The drugs are significantly less expensive than Acthar.

d. Rheumatoid Arthritis

109. Rheumatoid arthritis ("RA") is an inflammatory autoimmune disease in which the body's immune system targets itself, including the joints. RA patients can experience "flares" or "exacerbations" (collectively, "RA exacerbations"), which are periods of increased disease activity and are characterized by worsening RA symptoms.

110. RA exacerbations are not a separate disease from RA.

111. A standard treatment for RA exacerbations includes the administration of steroids, which can be available in brand name or general forms. The drugs are significantly less expensive than Acthar.

8. Dangers of Acthar for unapproved uses and doses

112. Acthar is a dangerous drug with wide ranging and potentially life-threatening adverse effects. Thus, its FDA-approved label specifically warns that patients taking Acthar may suffer the following adverse effects:

a. increased susceptibility to new infection and increased risk of exacerbation, dissemination or reactivation of latent infections, although signs and symptoms may be masked;

b. adrenal insufficiency;

c. Cushing's Syndrome;

d. elevated blood pressure;

e. masking of symptoms of other underlying diseases and disorders;

f. gastrointestinal perforation and bleeding;

g. behavioral and mood disturbances, including euphoria, insomnia, mood swings, personality changes, severe depression and psychosis;

h. comorbid diseases, such that symptoms of diabetes and myasthenia gravis may be worsened;

i. ophthalmic effects, such as cataracts, infections and glaucoma;

j. loss of endogenous activity;

k. enhanced hypothyroidism or liver cirrhosis for patients already suffering from these conditions'

l. negative effects on pediatric growth and physical development;

m. decrease in bone density; and

n. potential fetal harm in patients who are pregnant, or may become pregnant.

113. Additionally, the FDA-approved label warns that patients taking immune suppressive doses of Acthar should not be administered live or attenuated vaccines.

114. In view of Acthar's unusal safety profile, the FDA took the additional, non-standard step when it approved Acthar for the treatment of IS in 2010 of also approving a Risk Evaluation and Mitigation Strategy (REMS) that requires Mallinckrodt to distribute an approved Medication Guide with each prescription, and also to submit REMS Assessments to the FDA at periodic intervals following approval of the REMS. The approved Medication Guide elaborates on the serious and significant side effects associated with Acthar.

115. As set forth below, the case of Patient A demonstrates how Defendants scheme directly impacted patient safety, contrary to the FDA-approved Acthar label.

B. THE ACTHAR "DISTRIBUTION SCHEME"

1. Questcor acquires Acthar from Aventis.

116. In 2001, Questcor acquired Acthar from Aventis Pharmaceutical Products, Inc. ("Aventis") for only $100,000, but in 2014 Mallinckrodt acquired Questcor for approximately $5.9 billion.

117. In the July 27, 2001 Asset Purchase Agreement between Aventis and Questcor, Questcor acknowledged that there were risks in the transaction due to the limited approved indications for Acthar. Indeed, Questcor and Aventis held a meeting with FDA on February 7, 2001 in which such issues were discussed. Nevertheless, Questcor went through with the purchase.

118. Acthar's value was limited because it was the "gold standard" for treating only one condition, infantile spasms ("IS"). IS is a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to treat IS, further limiting its value. In 2010, the IS indication was approved by the FDA, and orphan drug status was granted.

119. Between 2001 – 2007, Acthar's primary sales were for the treatment of IS, despite its off-label indication.

2. Sigma Tau's Ownership and Control of Questcor, and the Launch of the "New Strategy".

120. In 2001, Questcor was floundering as a company until it got millions of dollars from Sigma Tau Finanziaria, an Italian drug conglomerate run by brothers Claudio and Paolo Cavazza, giving the Cavazzas and Sigma-Tau approximately 31% of the common stock outstanding as of March 15, 2002 and making them the largest shareholder in Questcor. Indeed,

in its 2001 10-K, Questcor admitted that "these shareholders can control the outcome of certain shareholder votes, including votes on election of directors, … and other significant corporate transactions."

121. In addition, the Cavazzas owned warrants to purchase another 2,559,494 shares of common stock, as well as a $2.0 million 8% convertible debenture, giving them even greater control over Questcor and its decision-making.

122. According to Questcor's public filings, the company reported the following:

> In April 2001, we entered into a Stock and Warrant Purchase Agreement with Sigma-Tau Finance Holding S.A. ("Sigma-Tau") pursuant to which Sigma-Tau purchased (i) an aggregate of 2,873,563 shares of common stock at a purchase price of $0.52 per share, for an aggregate purchase price of $1,500,000, and (ii) a warrant to purchase an additional 2,873,563 shares of common stock at a purchase price of $0.52 per share. In May 2001, as required under the rules of AMEX, we sought and received shareholder approval to allow for full exercise of the warrant. In July 2001, Sigma-Tau assigned the warrant to Paolo Cavazza and Claudio Cavazza, the principal shareholders of Sigma-Tau, who exercised the warrant in full, purchasing 2,873,563 shares of common stock at a purchase price of $0.52 per share, resulting in aggregate proceeds to us of $1,500,000 (including the $100,000 originally paid by Sigma-Tau to acquire the warrant).
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> In July 2001, concurrent with our agreement to acquire Acthar from Aventis, we entered into a Stock Purchase Agreement with Sigma-Tau pursuant to which Sigma-Tau purchased 5,279,034 shares of common stock at a purchase price of $0.66 per share, for an aggregate purchase price of $3,500,000.
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> In December 2001, we entered into a Promotion Agreement with VSL Pharmaceuticals, Inc., a private company owned in part by the principal shareholders of Sigma-Tau, to promote, sell and distribute the product VSL#3 in the U.S. In connection with this Promotion Agreement, we entered into two Stock and Warrant Purchase Agreements, one with Paolo Cavazza and one with Claudio Cavazza, to purchase (i) an aggregate of 640,000 shares of common stock for a purchase price of $1.50 per share (representing a twenty percent premium to our market price for the five days prior to execution of the Purchase Agreements), for an aggregate purchase price of $960,000, and (ii) warrants, at an aggregate purchase price of $300,000, to purchase an additional 1,800,000 shares of common

> stock at a purchase price of $1.75 per share before December 1, 2003. We issued the common stock related to this transaction in February 2002. Additionally, in connection with this transaction, we entered into a standstill agreement with Sigma-Tau whereby Sigma-Tau and its affiliates agreed to limit purchases of common stock on the open market to no more that 2,000,000 shares through July 2003. Assuming Sigma-Tau exercises its warrants in full, they would own approximately 34% (including the 640,000 shares of common stock issued in February 2002) of our outstanding common stock as of December 31, 2001.
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> On March 15, 2002, in two separate transactions, we issued $4.0 million of 8% convertible debentures to an institutional investor and Sigma-Tau. We will pay interest on the debentures at a rate of 8% per annum on a quarterly basis. The debentures are convertible into shares of our common stock at a fixed conversion price of $1.58 per share (subject to adjustment for stock splits and reclassifications). At the end of the term of the debenture, under certain circumstances, we have the option to repay the principal in stock and, under certain circumstances, we can also redeem the debenture for cash prior to maturity. The debentures mature on March 15, 2005. In conjunction with this transaction, we issued warrants to both the institutional investor and Sigma-Tau to acquire an aggregate of 1,518,988 shares of common stock at an exercise price of $1.70 per share. Both warrants expire on March 15, 2006….

123. Importantly, a few years earlier, Claudio Cavazza had earned notoriety, and 1 ½ years of probation, for his role in a 1993 scandal in which he admitted paying kickbacks to health officials to get Sigma Tau products onto Italy's national drug formulary at increasingly higher prices. He also reportedly delivered bribes on behalf of other drug companies.

124. But Claudio's criminal record, a record of bribes to force payers to overpay for prescription drugs, did not stop Questcor from taking the Cavazzas' money and ceding effective control of the company to the Cavazza brothers in conjunction with Questcor's acquisition of Acthar.

125. Instead, Questcor allowed the Cavazzas to build their ownership stake in Questcor to more than 30%, giving them substantial control over Questcor's Board of Directors.

126. The Cavazzas used that control to install one of their own, Gregg LaPointe, to the Questcor Board of Directors.

127. In 2001, LaPointe was the Vice-President of Finance for Sigma Tau Pharmaceuticals, Inc. of Gaithersburg, Maryland ("Sigma-Tau Pharma"). Sigma Tau Pharma was the wholly-owned, U.S. subsidiary of Sigma-Tau. By 2003, LaPointe was the Chief Operating Officer ("COO") of Sigma Tau Pharma. He was elevated to CEO in April 2007, in conjunction with his adoption of the below-described "new strategy" for Questcor's sale of Acthar.

128. With the Cavazzas effectively in control, and now with LaPointe on the Questcor Board, the situation was ripe for fraud and abuse with Acthar, the likes of which have never been seen before, especially with a prescription drug of such limited therapeutic value.

3. Mallinckrodt Adopts a "New Strategy" to Restrict Acthar Distribution and Aggressively Market Acthar for Unapproved Uses and Doses Through a Scheme of Kickbacks and Inducements

129. Acthar is a specialty pharmaceutical distributed directly to patients, like the beneficiaries of Local 420 and IUOE Local 542 in this case.

130. For decades, Acthar was distributed to any doctor, hospital, wholesaler or specialty pharmacy who requested the drug to treat seriously ill patients. After Questcor acquired the rights to Acthar, it initially maintained that broad distribution network.

131. However, on July 2, 2007, Mallinckrodt restricted its distribution from three wholesalers, termed Wholesalers "A", "B", and "C" in its 2007 10-K, to just Express Scripts.

132. The goal of this "new strategy" was to lock patients into receiving Acthar through one distribution channel controlled by Mallinckrodt, and to ensure prescription distribution and

payment through one source, UBC. UBC is Mallinckrodt's self-described "HUB" of operations for Acthar. Mallinckrodt has maintained this exclusive arrangement with UBC since 2007.

133. However, the original officers and directors of Mallinckrodt did not agree with the "new strategy". Accordingly, two Directors on the Mallinckrodt Board engineered a coup to take over the company, to replace the CEO and to have the company adopt the new strategy.

134. Mallinckrodt's "new strategy" was the brainchild of Defendant Gregg LaPointe, a critical member of the Questcor Board of Directors installed by the largest shareholders, the Cavazzas. LaPointe also served as a member of the Corporate Council of the National Organization for Rare Diseases ("NORD"), which served as an important player in Mallinckrodt's and UBC's scheme to minimize resistance and pushback by patients and physicians to Acthar's higher prices by serving as a leading distributor of free Acthar supplied by Mallinckrodt to patients who could not afford to pay the newly established new high prices.

135. LaPointe convinced Steve Cartt, Questcor's Chief Operating Officer and Executive Vice-President in charge of sales and marketing of Acthar at the time, that the company should implement the "new strategy" for Acthar.

136. Cartt and LaPointe approached then-Questcor Board member Don Bailey to garner his support for the new strategy. Their "offline discussions did not sit well with Questcor's President and CEO at the time, James L. Fares.

137. In February 2005, James L. Fares was appointed President and CEO of Questcor by the Board of Directors. According to Albert Hanson, the Chairman of the Board, "the Board sought an accomplished pharmaceutical executive with substantial expertise in selling and marketing pharmaceutical products." Chairman Hanson further explained the selection of Feres as follows:

> [T]he Board assessed each candidate's track record and capability to think creatively about Questcor's business. Such skills are critical in developing and executing a successful long-term strategy for a specialty pharmaceutical business. We looked for a talented executive who understood the specialty pharmaceutical market and had demonstrated the leadership skills necessary to create shareholder value. We believe that in Jim Fares we have found that executive. His successful track record in sales, marketing, business development, and general management, coupled with his energy and enthusiasm for pharmaceuticals, convinced us that we had found the right individual to lead Questcor.

138. Prior to joining Mallinckrodt, Feres held senior management positions at Merck, Athena Neurosciences and Elan Pharma. He founded and served as Sr. Vice President of Commercial Operations at Xcel Pharmaceuticals from 2001 – 2003. In his last position, he served as CEO and President of FGC Pharm/Novella Neurosciences. In sum, Feres was well qualified to lead a company like Mallinckrodt.

139. Feres resigned in May 2007, after taking the below-described 30% price increase for Acthar in February 2007. He was replaced by Don Bailey, whom the Board first appointed as Interim President, but then elevated to full-time President and CEO in conjunction with Mallinckrodt's adoption of the new strategy.

140. In sum, Bailey was not well qualified to lead a prescription drug company like Mallinckrodt. But he was willing to jettison responsible and ethical business practices in favor of the "new strategy", with unconscionable price increases [the Pricing Scheme] and an aggressive campaign of off label promotion fueled by misrepresentations and deception about Acthar's price, MOA, approved indications and doses, and value. For that, he was rewarded by being appointed the company CEO.

141. Mallinckrodt then signed contracts with Curascript and UBC in late June 2007 for the exclusive distribution of Acthar and exclusive operation of the HUB for ASAP.

142. Mallinckrodt and UBC then began to promote Acthar aggressively pursuant to the Pricing Scheme and Marketing Scheme detailed below. They did so to overcome resistance by providers, patients, and TPPs (like Local 420) to the high cost and limited value of Acthar.

143. Shortly thereafter, in July 2007, three Board members resigned, including the Chairman Albert Hanson.

144. In addition to CEO Feres, Mallinckrodt's Sr. Vice President of Strategic Planning and Communications, Eric Liebler, also quit. Liebler quit less than a year after being hired. He quit just three weeks after the "new strategy" was announced.

145. LaPointe also resigned within a week of the new strategy being launched, but not because he disagreed with the new strategy. Quite the contrary: his work on behalf of the Cavazzas was done. The Cavazzas had accomplished was they set out to do, engineering a coup at Questcor to take the company on an aggressive path centered around the new strategy and the three schemes detailed herein, the Distribution Scheme, the Pricing Scheme and the Marketing Scheme. Without LaPointe's installment on the Questcor Board, this would not have been possible.

146. These facts were confirmed by Questcor COO Steve Cartt on September 6, 2007, when he wrote to all senior staff at Questcor the following about LaPointe's departure:

> Subject: Lapointe departure
>
> Wanted to give you all a heads-up that Gregg LaPointe has left the Board of Directors (see attached link). This has been expected for some time actually, and is no cause for concern. Gregg joined the Board so that Sigma Tau could have some visibility on how Questcor was being run and the strategy going forward for the company. He actually as you can imagine ended up spending far more time on Questcor business over the last year than he ever imagined. Sigma Tau, our largest shareholder, is now comfortable with the company's path forward now, and is interested in having Gregg fully focused on Sigma Tau's own US business going forward, so the decision was made.

> Also, in case you were wondering, Gregg has been a big supporter of the pricing strategy from the very beginning, so his departure was not the result of any disagreement with strategy. Quite the contrary actually.
>
> Let me know if you have questions. Thanks, Steve.

147. It is believed and therefore averred that this mass exodus of leading executives and Board members was caused by Mallinckrodt's decision to adopt the "new strategy", with the Distribution Scheme, the Pricing Scheme and the Marketing Scheme as the hallmarks of an overarching scheme to raise Acthar prices, and overcome TPP resistance to high drug prices.

148. The decision to change the distribution, pricing and marketing strategies for Acthar was highly lucrative for all who supported it.

149. For instance, between 2006-2007, Don Bailey was permitted to purchase tens of thousands of shares of Questcor stock for $1.67 per share. He also received warrants to buy tens of thousands of additional shares of stock at just $0.44 per share. After the new strategy was pushed through, and the company started gouging patients and payers for Acthar, Bailey sold his shares, making tens of millions in profits.

150. Bailey's last warrant exercise and sale of Questcor stock took place in the summer of 2014, just prior to Mallinckrodt's purchase of Questcor. He exercised warrants to purchase 40,000 shares of common stock at $5.12 (at a total cost of $204,800). He then sold the same stock one month later at $91.96 per share (at a total price of $3,678,240). This was a profit of more than $3.2 million in one month!

151. All told, Don Bailey earned tens of millions of dollars in just over 7 years through his insider stock sales alone, not counting his lucrative executive and Board member package of salary and benefits.

152. The self-described "orphan drug strategy" worked as follows: despite the fact that Acthar was an older drug, Mallinckrodt would "re-launch" Acthar with a new, limited distribution system and a substantially higher price, to make it appear as if Acthar were a new product being launched as the only product indicated for IS, an off-label indication at the time.

153. The IS market was a captive market involving a life-threatening disease afflicting infant children. Like other debilitating or life-threatening, orphan conditions, for which there was only one, sole-source drug treatment, IS presented Mallinckrodt with an opportunity to leverage its position against a particularly fragile, powerless patient population in an extremely narrow market.

154. As a result, Mallinckrodt predicted that the IS market would likely be able to absorb a much higher price with little resistance. In contrast, Mallinckrodt feared that the market for drug treatments of other disease states, such as the MS market, would not tolerate such a high price. Nevertheless, Mallinckrodt only viewed the anticipated resistance to higher prices by patients and payors as a challenge to be overcome.

155. Mallinckrodt and UBC overcame such challenge in several ways, as part of a new marketing and sales scheme, including the following:

> (i) knowingly disregarding federal laws and FDA regulations prohibiting off-label marketing and promotion;
>
> (ii) knowingly misrepresenting the purported efficacy, safety and value of Acthar for the treatment of unapproved conditions and unapproved doses in promotional and marketing material not submitted to, reviewed by, or approved by the FDA;
>
> (iii) failing to disclose and submit to the FDA all of their promotion, advertisements and marketing materials, as required by law;
>
> (iv) promoting the sale of Acthar for uses that were not proven to be safe or effective, as required by law;
>
> (v) promoting the sale of Acthar for doses that were not proven to be safe or

effective, as required by law;

(vi) willfully underreporting adverse events, as required by law;

(vii) utilizing improper, false and misleading comparative marketing tactics, such as comparing Acthar to prednisone, and including unsubstantiated superiority and value claims; and

(viii) improperly compensating healthcare professionals with free vials of Acthar, speaking and consultant fees and benefits, and other kickbacks as an inducement to induce them to promote and prescribed Acthar to their patients.

(ix) operating patient assistance programs as a means to secretly channel funds to third parties to pay for patient copay obligations, to remove patient complaints about the high costs of Acthar, and to force TPPs like Local 420 to pick up the balance of the Acthar bill.

156. The new pricing established by Mallinckrodt under the Pricing Scheme was only limited by what Mallinckrodt predicted that payors, like Local 420, would be willing to bear. This was because the Marketing Scheme adopted at the same time ensured that the promotional message delivered by UBC, as well as Mallinckrodt sales representatives and MSL's, was false, misleading and deceptive, and backed by unlawful kickbacks and inducements.

157. Mallinckrodt Executive Vice-President, Steve Cartt, admitted "'[w]e did some market research,' . . . [t]alking to physicians and others about pricing 'gave us some comfort that the [new] strategy would work, and physicians would continue to use the drug, and payers would pay' . . . . 'The reality was better than we expected.'"[4]

4. <u>The Acthar Support & Access Program and the UBC "HUB"</u>.

158. One of the primary means by which Defendants carried out their unlawful scheme and conspiracy was through a program known as the "Acthar Support & Access Program" or "ASAP." This program was structured to ensure that Mallinckrodt could ship its Acthar directly

[4] Milt Freudenheim, *Benefit Managers Profit by Specialty Drug Rights*, New York Times, C1, April 19, 2008 (titled The Middleman's Markup in New York Print Ed.)(hereinafter, "*Fruedenheim*").

to patients, and then receive guaranteed payments directly from the TPPs who provide prescription drug coverage for their beneficiaries.

159. The ASAP was adopted by Mallinckrodt and UBC in 2007, as part of the "new strategy". UBC's predecessor became the exclusive operator of the ASAP program for Mallinckrodt.

160. Under the ASAP, all Acthar prescriptions are routed through UBC to patients, and all Acthar payments are coordinated by UBC to Mallinckrodt.

161. This process is generally laid out in the Acthar Start Form provided by Mallinckrodt (at Exhibit A hereto).

162. Once the patient (or their physician) seeks a prescription of Acthar, they are directed to UBC by Mallinckrodt's sales representatives, MSLs or KOLs. They are then required to fill out and fax back to UBC the Acthar Start Form in order to obtain Acthar. There is no other way to get Acthar.

163. Upon receipt of the Acthar Start Form, UBC confirms the prescription by the provider and the associated specialty pharmacy, and then confirms the patient's insurance coverage or other source of payment. UBC then arranges for the Acthar to be delivered directly to the patient by CuraScript.

164. Copies of the Acthar Start Form are attached to the Strunck & Pratta Complaint at Exhibit "H" and "I". These Qui Tam Relators have confirmed that this is the process for Acthar.

165. The Acthar Start Form requires the patient and the physician to authorize the prescription as "medically necessary", and to payment as appropriate before Mallinckrodt will ship the Acthar to the patient. Mallinckrodt have used a version of the Acthar Start Form for all

year from 2007 through the present. For this entire time period, such forms are required to be faxed to UBC, via the used of the wires.

166. The Acthar Start Form consists of 3 sections: (1) a section requiring signature by the "HCP" (or health care professional); (2) a patient authorization requiring signature by the "patient or legal representative"; and (3) information concerning Acthar indications and usage. The required signature of the patient authorizes "Mallinckrodt and its agents" to do a number of things in relation to the prescription and distribution of Acthar. It further authorizes Mallinckrodt and its agents, "including Mallinckrodt reimbursement support personnel and United BioSource Corporation ("UBC") or any other operator of the Acthar Support Access Program on behalf of Mallinckrodt (collectively, 'Designated Parties')" to provide Acthar and receive payment, among other things.

167. Specifically, the patient authorizes Mallinckrodt and UBC, its "Designated operator", "to provide certain services to [the patient], including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injecting training." In other words, the patient directly authorizes UBC, as Mallinckrodt's agent, to ship Acthar directly to them, and to receive payment from both the patient (for the co-pay) and the TPP prior to obtaining the medication.

5. Direct Injury of Plaintiff and the Class.

168. By the above-stated arrangements, Acthar product flows from Mallinckrodt to the patient, while the money flows from the patient and payor back to Mallinckrodt.

169. Mallinckrodt only "consigns" the Acthar to CuraScript, meaning that Mallinckrodt remains at risk for the sale of the product until it is shipped. Mallinckrodt maintains all right, title and interest to the Acthar until it is approved for delivery by UBC to the

patient and payment is assured by the TPP. Both possession and title pass to Acthar pass from Mallinckrodt to the patient and TPP, only after they both agree to pay for it via the Acthar Start Form and UBC's sign-off. UBC's role is to ensure that Mallinckrodt's "risk" is minimal because it will not authorize shipment until payment by the TPP is confirmed. At no time is either CuraScript or UBC at risk for the Acthar sold by Mallinckrodt.

170. In this way, TPPs like Local 420 and IUOE Local 542, along with other similarly situated members of the Class, are directly harmed by the conduct of the Defendants, because their beneficiaries receive the Acthar directly from Mallinckrodt, via its designated consignees, at their homes to be self-injected, and they make their co-payments, along with the TPPs, directly back to Mallinckrodt through this same arrangement.

171. This is a distinguishing feature of specialty drugs in general, from other brand name and generic drugs available at retail pharmacies, who received the drugs from wholesalers, who directly contract with drug manufacturers. Here, Mallinckrodt and UBC removed all the middlemen. There are no wholesalers or retailers between the patients and TPPs and the Defendants.

172. Further, Plaintiff and TPP members of the Class have paid the inflated AWPs directly set and charged by Defendants. As a result, their injury is both cognizable – economic injury from a price overcharge – and direct – paying the price set and charged by the Defendants sued. The Class does not include any other potential payors who may have paid some other price than the inflated AWPs for Acthar.

173. Mallinckrodt and UBC also uniquely interact directly with TPPs and their beneficiaries in this case to ensure their scheme is successful. Beyond direct consultation, they provide "Home Injection Training Services" or "HITS", by which Mallinckrodt pays to have a

nurse visit the patient to teach them how to self-inject the Acthar. UBC arranges for HITS, and tracks all such interactions through a database maintained for Mallinckrodt. All bills for such HITS are paid by Mallinckrodt, who is happy to provide free injection training to remove any potential obstacle to a patient taking Acthar.

174. The Acthar Start Form (Exhibit "A" hereto), by which all Acthar is prescribed, has section for the provider to request HITS for the patient.

175. These direct interactions between the Defendants and the Class give Plaintiff and the Class standing to sue on all counts. At a minimum, they raise serious fact questions about the uniqueness of Defendants' scheme to allow this case to proceed to discovery.

C. THE ACTHAR "PRICING SCHEME"

1. Defendants raise the AWPs for Acthar, and charge such prices to TPPs, without regard for the lack of proven safety, efficacy or value of the drug to treat the diseases for which they market and sell Acthar.

176. Mallinckrodt acquired the rights to Acthar from Aventis in July 2001.

177. At the time of its acquisition, the end payor price of a vial of Acthar charged to TPPs, like the Plaintiff, was approximately $40.00.

178. After acquisition, Mallinckrodt raised the per-vial price substantially. By September 2001, Mallinckrodt raised the list price for Acthar, or the wholesale acquisition cost ("WAC"), to $748.16. It raised the end payor price, or the average wholesale price ("AWP"), to $935.20.

179. Like other brand name, injectable drug manufacturers, Mallinckrodt adopted a 25% markup factor for its AWP for Acthar. In other words, once Mallinckrodt sets a new WAC, the AWP is calculated at 25% above the new WAC.

180. From 2001 until Mallinckrodt executed its new strategy in 2007, the Acthar WAC grew from $748.16 to $1,650.23, while the AWP grew from $935.20 to $2,062.79 (25% higher than the WAC).

181. The below table reflects the WAC and AWP price changes (and the percentage increase) as implemented by Mallinckrodt from 2001 through February 2007, and as charged by UBC:

DATE	WAC	AWP	% INCREASE
Sept. 21, 2001	$748.16	$935.20	-
June 24, 2002	$782.60	$978.25	4.6
April 1, 2003	$859.20	$1,074.00	9.787
March 1, 2004	$902.00	$1,127.50	4.98
January 1, 2005	$988.00	$1,235.00	9.53
April 1, 2005	$1,037.20	$1,296.50	4.98
January 1, 2006	$1,120.40	$1,400.50	8.0
October, 1, 2006	$1,232.44	$1,540.55	10.0
December 21, 2006	$1,269.41	$1,586.76	3.0
February 2, 2007	$1,650.23	$2,062.79	30.0

182. The double-digit price increase in 2005 and 2006 were not enough, nor as the 30% price increase in February 2007. Mallinckrodt's greed required more.

183. When Mallinckrodt implemented its new strategy with UBC on August 27, 2007, they raised the WAC for Acthar from $1,650.23 to $23,269.00. They also raised the AWP for Acthar from $2,062.79 to a staggering $29,086.25 – representing a 1,310% increase in the span of a month, and a 72,615% increase from the time Mallinckrodt first acquired the drug.

184. Until Mallinckrodt obtained FDA approval for the IS indication in 2010, the price of Acthar remained relatively stable. However, in 2011, Mallinckrodt increased the price of Acthar three times: by 5% on January 3, 2011, by another 5% on June 1, 2011, and then by 6.5% on December 27, 2011. These three price increases totaled a staggering 16.5% in one year. As of 2012, Acthar's end payor price/AWP stood at $34,150.00.

185. But Mallinckrodt and UBC were wary of TPP's increasing concerns about Acthar's price and lack of proven value for the various indications being promoted. A poignant example is the attempted price increase in September of 2012.

186. In September 2012, Mallinckrodt desired to take another 5% price increase. The decision to raise the Acthar price was made by Questcor's COO Steve Cartt in early September.

187. However, on September 19, 2012, health insurer Aetna, announced that it would cut back reimbursements for Acthar, due in part to the lack of evidence of Acthar efficacy for various disease states.

188. Questcor's stock plummeted 56% the same day as the Aetna announcement. Within a week, Questcor's stock had fallen another 37%.

189. Mallinckrodt scrambled to place the intended price increase "on hold for now", due to the Aetna situation. It so advised Curascript and UBC, which both agreed.

190. This price increase was later taken by the Defendants on June 7, 2013, when the Acthar WAC was increased 5% to $30,120.00 and the Acthar AWP was increased 5% to $37,650.

191. In 2014, Defendants resumed their aggressive price increase strategy, just prior to Mallinckrodt plc's $5.9 billion acquisition of Questcor. But they continued to conceal the truth, lying to the public about the real reasons for the exorbitant price increases.

192. On January 16, 2014, the Acthar WAC and AWP were raised 5%, to $31,626 and $39,532.50, respectively.

193. Prior to Questcor's acquisition by Mallinckrodt plc in 2014, Questcor had planned an additional 5% increase for Acthar in December 2014. This would have meant a total percentage increase of 10% for the year.

194. However, after the acquisition, Mallinckrodt raised the planned increase to 8.9%, or 13.5% for the year.

195. In the interim, the Executive Committee ("EC") of Mallinckrodt met. The EC consists of the senior management of Mallinckrodt, including President and CEO Mark Trudeau and Executive Vice President and Chief Commercial Officer Hugh O'Neill.

196. COO O'Neill raised the matter of the 8.9% price increase with the EC on Friday December 12, 2014, and it was decided by the Mallinckrodt leadership team to "change[] the magnitude" of the pricing action, reducing the proposed increase from 8.9% to 2%. The EC did this in order to take advantage of an "opportunity for breakthrough pricing strategies" in the future.

197. It is believed and therefore averred that such pricing opportunity was presented by Questcor's prior acquisition of Synacthen, a synthetic version of ACTH.

198. Questcor had completed its acquisition of Synacthen in 2013.

199. As a result of such Synacthen acquisition, Mallinckrodt was confident that reducing the planned 8.9% Acthar price increase in late 2014 to little more than the consumer price index [which stood at about 1.7% in 2014] -- causing a $26 million shortfall in the forecasted revenues [based on the 5% increase that was "baked in" for December] -- would not negatively affect the company moving forward. This decision, while ostensibly made against Mallinckrodt's economic self-interest in the short term, was made to further enhance their profits in the long run.

200. Accordingly, with the direct input and hands-on decision-making by President and CEO Trudeau, Mallinckrodt reduced its December 2014 Acthar price increase to 2%. This

led to a WAC increase to $32,260.00 and an AWP increase to $40,325.00, respectively, on December 16, 2014.

201. Under Mallinckrodt plc's stewardship, the AWP of Acthar has continued to rise in to well above $40,000 in 2018, when Local 420 began paying for it, despite Mallinckrodt's misrepresentations about Acthar's price.

202. In 2018, Mallinckrodt's CEO, Mark Trudeau, deliberately lied to the public in a press release. He willfully misrepresented that "[t]he current 'list price' per vial for the drug is $36,382, not the higher numbers which have appeared in various reports, and Mallinckrodt discounts this list price to both public and private payers." *See* Mallinckrodt 2018 Statement at Exhibit "D" hereto. This statement was false, misleading and deceptive.

203. The price paid by "private payers", like Local 420 and the Class of TPPs in this case, is the AWP. As set forth above, that price has been in excess of $40,000 since 2014. Mallinckrodt does not "discount" that price to Local 420, or any other TPP, as claimed.

204. If Mr. Trudeau was actually representing that the WAC for Acthar was $36,382 as of June 2018, which is not the price paid by "private payers" like Local 420, then the AWP paid by private payers would have been actually a staggering $45,477.50, based on the historical 25% markup Mallinckrodt has employed for its Acthar AWPs since the inception of its ownership in 2001.

205. Since the acquisition of Acthar in 2001, the end payor price of Acthar has grown over 100,000% reflecting the precipitous rise in the value of the Acthar assets from $100,000 in 2001 to $5.9 billion in 2014 – a 5,899,900% increase in value. Mallinckrodt has continued to deceive payors like Local 420 and the TPP Class about the actual prices of Acthar, and the reasons for its many staggering price increases.

206. In fact, in direct response to a lawsuit filed against Mallinckrodt in April 2017 by the City of Rockford, Illinois, Mallinckrodt issued a public statement, claiming to "set the record straight" about Acthar pricing and other issues. *See* Mallinckrodt 2018 Statement at Exhibit "D" hereto. This press release is replete with misrepresentations and deliberate falsehoods that only continues to deceive Local 420 and the Class about Acthar pricing and the actual reasons for the high Acthar prices.

207. The 2018 press release was issued by the company CEO Mark Trudeau who falsely, misleadingly and deceptively claimed that the "price of H.P. Acthar Gel today is $38,892, before discounts provided to payers." Id.

208. However, when Local 420 paid for Acthar in 2018, the Acthar AWP was well over $40,000.00. In fact, the AWP for Acthar had been raised by Mallinckrodt to $40,325.00 on December 16, 2014, 4 years before Trudeau willfully made his materially false statement about Acthar pricing.

209. Today, the price of Acthar stands at over $43,000.

210. Mallinckrodt has conspired and agreed with UBC, and others, to conduct a fraudulent scheme and conspiracy to deliberately inflate the AWPs for Acthar, to maintain such high AWPs for Acthar in the face of complaints by patients and TPPs, like Local 420, to communicate such inflated prices, and to circumvent patient and payor concerns about Acthar's high prices through the Distribution and Marketing Schemes alleged herein. As Defendants well know, the AWP is used by both government and private assistance programs for prescription drug reimbursement.

211. Government and private assistance programs, like those of Local 420 and the Class, have used the AWPs published in pharmaceutical industry publications, such as the Red Book and Medispan, for years as a basis for reimbursement, in whole or in part.

212. These publications set forth the false AWPs for Acthar, as reported with each price change by Mallinckrodt. In periodically announcing the AWPs for Acthar, the publications simply published the prices supplied to them by Mallinckrodt. Mallinckrodt knew that it could, and did directly, control and raise the AWP for Acthar at any time simply by forwarding to the pricing compendia a new and higher AWP.

213. This Pricing Scheme allowed Mallinckrodt to control, in conjunction with its Distribution and Marketing Schemes, its profit levels, and the profits of its HUB, UBC, by the direct manipulation and reporting of the Acthar AWP.

214. Years before Mallinckrodt and UBC engaged in their Pricing Scheme to manipulate the Acthar AWPs to increase their profits, in 2003, the Office of Inspector General ("OIG") admonished, "[i]f a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated." In re Pharm. Ind. Average Wholesale Price Litig., 491 F.Supp. 2d 20, 39-44 (D. Mass. 2007). Ironically, this published decision appeared the same month in 2007 that Mallinckrodt and UBC signed their first of many conspiratorial agreements to manipulate and communicate the AWP for Acthar.

215. Plaintiff is not alone in its charge of deceptive conduct against Mallinckrodt. In April 2015, Mallinckrodt settled a securities fraud class action brought by its investors against the company in January 2013 in the United States District Court for the Central District of California for the sum of $38 million. The securities lawsuit charged the company with, inter

alia, "issu(ing) false and misleading statements about the effectiveness of, and prospects for, Questcor's sole product, Acthar." The court denied in part the Defendants' motions to dismiss, allowing certain claims to proceed. The court then granted class certification in November 2014.

216. Following the settlement, Mallinckrodt's CEO Mark Trudeau suggested to investors on October 6, 2015 that drug prices "should be reflective of the value that you deliver to the marketplace."

217. However, following this settlement, and the filing of the Rockford lawsuit, leading executives at PBM Express Scripts (which owned UBC) conceded that Acthar is not worth what Mallinckrodt is charging for it, and what TPPs like Local 420 and IUOE Local 542 have been paying for it, especially for the treatment of MS, NS and RA. Despite this, neither Mallinckrodt nor UBC have changed their ways.

2. The Views of Express Scripts' Senior Management On the Lack of Acthar "Value" for the Prices Charged.

218. When Mallinckrodt chose to increase the price of this 50-plus year-old medication, the leading PBM, Express Scripts, did not push back. This likely due to its ownership of Curascript and UBC, which were both subsidiaries of Express Scripts at the time.

219. However, when confronted about the 2007 price increase in later years, Express Scripts' Chief Medical Officer Steve Miller stated that "[t]he increase was a manufacturing decision. I can't comment on it."[5]

220. On May 19, 2017, just weeks after Mallinckrodt was sued by the City of Rockford in early April 2017 for, inter alia, price fixing, Express Scripts senior officers made comments about the "somewhat controversial" drug Acthar on a private investor conference call hosted by

[5] *Freudenheim*, *supra*.

Citi.[6] The Citi interviewer stated, "it's been in the news as – given the pricing around the drug over the past – I don't know – 12 months at least," and then asked for "any thoughts around … how that can be managed and how you see cost of the playing out?" Citi Transcript at 12.

221. In response, Express Scripts' Senior Vice President, Supply Chain and Specialty Pharma, Everett Neville stated:

> I don't think [Acthar is] a very great [drug] – ***it's a pretty poor drug with a very limited need*** and certainly [Express Scripts Chief Medical Officer, Dr,] Steve [Miller] could comment. He's a doctor and I'm just a really bad pharmacist.
>
> …[Y]ou know, and Steve, you could chime in here too, but I think Steve and I both would agree, and ***I think everybody in our company would agree, that the product is vastly overpriced for the value***. ***We don't set the price.*** We've told [Mallinckrodt] that. I personally told [Mallinckrodt's] management team that their drug is hugely overpriced. I know Steve has as well.

Citi Transcript at 12 (emphasis added) (brackets added).

222. Dr. Miller stated that he was in "100% agreement with [Mr.](Everett)." Citi Transcript at 12 (brackets added). He added, "[i]f you look at the data, the indications for the drug are really – while it had, in the compendium, it's listed under a lot of indications, its real use should be very, very limited. It's an old drug. There's better products in the marketplace…". Citi Transcript at 12-13.

223. One of the areas where Acthar should be limited is the treatment of rheumatic disorders, like the condition suffered by the beneficiary of Local 420.

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[6] *See* Conference Call Transcript of call hosted by the Citigroup Healthcare Team on May 19, 2017 at 11:00a.m. est, with Dr. Steve Miller, Chief Medical Officer from Express Scripts, and Mr. Everett Neville, Senior Vice President of Supply Chain and Specialty (***"Citi Transcript"***).

224. Indeed, in December 21, 2017, Express Scripts provided an updated "Prior Authorization Policy" for Acthar, effective January 2018 (hereinafter "2018 Prior Authorization ***Policy"***).

225. The 2018 Prior Authorization Policy admitted that Acthar "may be used for … rheumatic disorders as an adjunctive therapy for short-term administration for an acute episode or exacerbation (in psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis [selected cases may require low-dose maintenance therapy]…".

226. The adult beneficiary of Local 420 was prescribed Acthar for a rheumatic disorder, but not for an RA exacerbation and not in low-dose form, as required.

3. Mallinckrodt Acquires Acthar from Aventis at a Low Price Reflective of its Lack of Market Value.

227. In 2001, Mallinckrodt, then Questcor, acquired Acthar from Aventis Pharmaceutical Products, Inc. ("Aventis") for only $100,000. This low price was reflective of the lack of market value for Acthar for the treatment of disease.

228. But in 2014, seven years after Questcor embarked on its "new strategy" for Acthar, Mallinckrodt acquired Questcor for approximately $5.9 billion.

229. In the July 27, 2001 Asset Purchase Agreement between Aventis and Questcor, Questcor acknowledged that there were risks in the transaction due to the limited approved indications for Acthar. Indeed, Questcor and Aventis held a meeting with FDA on February 7, 2001 in which such issues were discussed. Nevertheless, Questcor went through with the purchase.

230. Acthar's value was limited because it was the "gold standard" for treating only one condition, IS. IS a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to

treat IS, further limiting its value. As described above, the IS indication was not approved by the FDA until 2010. Between 2001 and 2010, IS was an *off-label indication* which Mallinckrodt actively marketed.

231. Between 2001 and 2007, Acthar's primary sales were for the treatment of IS, despite its off-label indication.

232. Consequently, because Mallinckrodt's primary business concerned the off-label marketing and sales of Acthar for IS, it is not surprising that it sought to expand upon such business model in other off label areas, once the IS indication was approved.

233. After the "new strategy" was adopted, Mallinckrodt expanded its marketing for other unapproved uses and doses in MS, NS, SLE and RA. As a result, sales expanded exponentially in these areas, expanding the profits of the company, all due to Mallinckrodt's company-wide campaign of off label promotion.

234. It was only because of the profits achieved in the areas other than IS that Questcor was deemed worth nearly $6 billion to Mallinckrodt. Consequently, Mallinckrodt has continued to advance the distribution, pricing, marketing and sales schemes initiated by Questcor. These are not "legacy" matters, as Mallinckrodt has falsely claimed. Instead, they have been engrained in Mallinckrodt's business and corporate culture since the early 2000s.

235. For that reason, Local 420 and the Class seek declaratory and injunctive relief against Mallinckrodt to put an end to the ongoing schemes for the benefit and future protection of patients and private TPPs, regardless of whether the federal government chooses to settle with Mallinckrodt. The putative Class described below expressly excludes government payors who have settled with Mallinckrodt.

D. THE ACTHAR "MARKETING SCHEME".

236. The Marketing Scheme in this case is identical to the scheme alleged in the Strunck & Pratta and Clark Complaints, and as amended in the U.S. Complaint in Intervention all filed and pending in this Court. The only difference is the affected class of plaintiffs – all private payors as opposed to the government payors in the government's case.

237. To duplicate those factual averments would exponentially and unnecessarily grow the length of this already lengthy Complaint.

238. Nevertheless, Local 420 summarizes those averments herein to make clear that it and the Class of TPPs it seeks to represent suffered harm as a result such Marketing Scheme.

1. As Part of its "New Strategy", Mallinckrodt Creates a Team of Highly-Trained "Medical Sciences Liaisons" to Promote the Sale of Acthar at High Prices Through a Campaign of Misrepresentations and Deception in Conjunction with KOLs.

239. As part of the new strategy in 2007, Mallinckrodt created a new position within the company: "Medical Science Liaison" or "MSL" were highly trained sales employees who were deployed to speak directly to doctors about the safety and efficacy of Acthar for unapproved uses and doses.

240. Mallinckrodt also employed MSLs to provide periodic training to employees of UBC.

241. Such training included information about Acthar's approval uses and doses, as well as its purported safety and efficacy for unapproved uses and doses based upon Mallinckrodt-sponsored "open label" clinical studies, usually conducted by Mallinckrodt-paid KOLs.

242. In the Strunck & Pratta Complaint, they detail the important role the new MSLs played in the Mallinckrodt and UBC schemes alleged. Specifically, the allege:

> Another tactic employed by Questcor to promote H.P. Acthar Gel off-label is to use its Medical Science Liaisons ("MSLs") as an end-run around sales representatives' duty to lawfully promote the drug. Questcor's use of MSLs in this manner is a way for the company to make the unlawful promotional activities for H.P. Acthar Gel appear lawful. *See e.g.* 21 C.F.R. 99.101. et seq.
>
> Medical Science Liaisons are supposed to talk with physicians only about science-to-science issues, and only when those discussions are initiated by the physician. Their primary role is to engage in non-promotional medical activities, and they are not supposed to engage in product promotion. Thus, a sales representative is not permitted to use an MSL as a conduit through which to initiate and pursue off-label promotion activities with physicians.
>
> The law notwithstanding, Questcor erects no wall between its medical and sales staffs, and actively encourages its MSLs to probatively participate in promotional activities. Medical Science Liaisons routinely accompany Questcor sales representatives on their sales calls.
>
> Questcor encourages its sales representatives to probatively partner with MSLs to increase H.P. Acthar Sales growth. Commonly, the sales representative will initiate an off-label discussion, and then the MSL will complete the discussion. On other occasions, sales representatives ask their MSL colleagues to contact physicians who are reluctant to prescribe H.P. Acthar Gel for off-label uses in order to attempt to overcome that reluctance whether or not the physician initiated the off-label discussion or requested further information. Again, Questcor ignores that MSLs are not permitted to engage in promotional activities.

Strunck & Pratta Complaint at ¶¶ 142-145.

243. The Relators then proceed to explain the critical role of these MSLs in promoting the off-label use of Acthar, especially for the unapproved, in effective and harmful 5-day dose prescribed to MS patients, like the patients of IUOE Local 542 described below. The specifically allege as follows:

> **Five Day Course of Treatment Was Ineffective and Harmful to Patients**
>
> Many physicians have rightfully rejected Questcor's efforts because the 5-day protocol is not supported by any credible evidence, and because experimenting with it cannot be justified in light of its cost and potential for patient harm. However, many physicians have been persuaded to

switch from Solu-Medrol to a 5-day course of treatment with H.P. Acthar Gel – in large measure due to the valuable inducements provide to them by Questcor, as described herein.

In Relator Strunck's experience, approximately half the doctors he persuaded to prescribe H.P. Acthar Gel for a five-day course of treatment had to order repeat prescriptions in as few as two to three months due to patient relapse, even though patients treated with Solu-Medrol typically relapse only after twelve to eighteen months. Relator Strunck knows this issue was widespread, because it was regularly was [sic] discussed during regional sales team conference calls. In Relator Pratta's experience, she experienced the same reactions from patients who doctors use the five day [sic] course of treatment.

Questcor's decision to promote H.P. Acthar Gel only for a five-day course of treatment came at the detriment of patients and patient safety. The issue was routinely discussed during regional sales calls and national sales meeting, Questcor knew that although a typical patient treated with Solu-Medrol for five days would relapse in twelve to eighteen months, and that a typical patient treated with H.P. Acthar Gel would relapse in as few as two to three months.

Thus, the cost to treat a typical patient with Solu·Medrol would be less than $5,000 over a five-year period (approximately four treatment cycles), but the cost to treat the same patient with H.P. Acthar Gel would be almost $700,000 (approximately 30 treatment cycles). As an example, at the Regional Sales Meetings on March 7th-8th in 2013, held in New Brunswick, New Jersey Blainy Creasy, the region's new Medical Science Liaison (MSL) gave a scientific talk about Acthar and its new mechanism of action (MOA) and how they intend to position it in the physician's offices. Stacy Clancy said that "*even though we sell 5 day, the docs are finding out that it is not working and some patients need another vial.*"

Plainly, promoting a five-day course of treatment with H.P. Acthar Gel inured to the patient's financial detriment and, more importantly, to the detriment of the patient's health and well-being. Questcor promoted the five-day treatment cycle in order to get both the physician and the patient "hooked" on the substantially more expensive H.P. Acthar Gel in lieu of Solu medrol [sic].

Strunck & Pratta Complaint at ¶¶ 146-150.

2. Mallinckrodt Uses KOLs to Create Biased Clinical Data to Deceive Patients and TPPs, and to Cultivate High Acthar Prescribers as "Spokes-Doctors".

244. In view of the extremely limited clinical data that existed at the time of Acthar's approval in 1952, and since that time, Mallinckrodt has been forced to try to create data to support its false and misleading marketing effort about Acthar's "value" to treat disease beyond the narrow indications on its label.

245. Mallinckrodt cultivated so-called "Key Opinion Leaders" or "KOL's" create such data, and then disseminated such data to other doctors through their highly-compensated spokes-doctors.

246. As ProPublica has reported, and as demonstrated below by a few examples, dozens of high prescribers of Acthar have been cultivated as spokes-doctors and paid tens of thousands of dollars for their work on behalf of Mallinckrodt in this regard.

247. These KOLs are paid by Mallinckrodt to cultivate a narrow group of high prescribers of Acthar, some of whom are also engaged by Mallinckrodt to generate clinical data based on their own patient populations to support Acthar's off-label uses and doses, without FDA oversight, input or scrutiny. The company then widely disseminates the results of such anecdotal studies as part of its vast marketing campaign to convince doctors that Acthar is safe and effective for unapproved uses.

248. As similarly alleged in the opioid litigation, in which Mallinckrodt has been sued as a defendant in MDL 2804 (pending in an Ohio Federal District Court) and in state courts throughout the country, including Pennsylvania, Mallinckrodt cultivated a select circle of doctors who were chosen and sponsored for their pro-Acthar messages in order to create "the grave misperception science and legitimate medical professionals favored the wider and broader use"

of Acthar. These KOLs were used to present the appearance that unbiased and reliable medical research supporting the broad use of Acthar for neurology, nephrology and rheumatology had been conducted and was being reported on by independent professionals. *See In re: National Prescription Opiate Litigation*, Case No. 1:17-md-02804-DAP, N.D.Ohio, Doc. No. 1025 (Report and Recommendation dated October 5, 2018) at 6-7.

249. The publications of many of these physicians, including those of Dr. James James A. Tumlin of Tennessee described below, were funded by Mallinckrodt as they supported the position that Acthar for broad use in neurology, nephrology and rheumatology was appropriate, all the while knowing these statements were false, misleading and deceptive.

250. Mallinckrodt utilized KOLs, like Dr. Tumlin, to develop "open label" clinical data to support Mallinckrodt's promotion of Acthar for new indications in nephrology, neurology and rheumatology.

251. "Open label" clinical trials, unlike the FDA-approved trials described above, do not attempt to disguise the drug being studied, meaning that no standard treatment or placebo is utilized. This leans towards bias, as both the patient and the physician are aware of which groups are receiving what type of treatment. The results are thus unreliable.

252. In NS, for instance, Mallinckrodt was aware as early as 2009 that doctors were nearly unanimous in their expression of a need for clinical data to support the efficiency and safety of Acthar in NS, as well as the need for clarification on the appropriate dosing regimen. Working with KOLs who expressed interest in generating such data became a major focus for Mallinckrodt MSLs in 2009 and beyond.

3. JAMA Study of Mallinckrodt KOLs, and Connection Between Kickbacks Payments and Higher Acthar Prescriptions.

253. In June of 2018, a team of researchers and concerned clinicians used Medicare and Medicaid data to investigate the frequency of use and overall expense of Acthar. To characterize payments from Mallinckrodt to physicians who prescribe Acthar, these researchers and clinicians conducted a cross-sectional analysis of data from CMS, including the Medicare Part D Public Use Files. Focusing on 2015, the researchers used the database to identify physicians, and their specialties, who prescribed Acthar more than 10 times that year, characterizing them as "frequent prescribers."

254. Their study, published in JAMA Network Open, found that in 2015 only 300 providers wrote more than 10 prescriptions for Acthar. Of those 300 prescribing providers of Acthar, 235 of them were rheumatologists, neurologists, or nephrologists.

255. Further, among those 235 rheumatologists, nephrologists and neurologists who issued more than 10 prescriptions for Acthar in 2015, 88% (207/235) received payments from Mallinckrodt – with more than 20% of those frequent prescribers receiving more than $10,000 – despite Acthar's considerable cost and the dearth of evidence to support its use.

256. Some physicians prescribing Acthar were paid as much as $56,000-$138,000 by Mallinckrodt for activities related to Acthar, making such payments equivalent to the salary of full-time employees of Mallinckrodt.

257. Indeed, as noted by one of the researchers and clinicians in the JAMA study, Dr. Daniel M. Hartung, "[e]xpensive therapies with uncertain or insufficient evidence supporting their use should be particularly scrutinized." He further noted that, "[t]he continued growth in corticotropin [Acthar] use is peculiar given its very high cost, widespread negative media coverage, and notable lack of evidence supporting its use over lower-cost synthetic

corticosteroids. Our experience suggests aggressive marketing of the drug partly accounts for increasing use."

258. The JAMA study also noted an association between providers who received higher compensation and their writing more Acthar prescriptions—and the Acthar prescriptions written by these frequent prescribers accounted for $200 million in Medicare spending during the period that the study examined.

259. Indeed, this study also found that from 2011 to 2015, spending on Acthar increased ten-fold, totaling more than $1.3 billion for just several thousand Medicare patients. Upon information and belief, and given the continued marketing of Acthar by Mallinckrodt pursuant to the marketing scheme alleged by the Qui Tam Relators, those numbers have increased since 2015.

260. The conclusion of the JAMA study was that most nephrologists, neurologists, and rheumatologists who frequently prescribe Acthar received Acthar-related payments from Mallinckrodt, suggesting that financial conflicts of interest may be driving the prescription and use of Acthar. Indeed, as noted by Dr. Hartung, "we observed a positive association between the amount of money paid to these prescribers, their prescribing intensity, and corticotropin [Acthar] expenditures in the Medicare program with a return on investment for Mallinckrodt of about 5:1."

261. Consistent with the JAMA study's conclusions, in October of 2014, Mallinckrodt had a briefing with its investors. At that briefing, Dr. Gary Phillips, the Senior Vice President, and President of Mallinckrodt's Autoimmune and Rare Disease Business, pledged, "[t]he one thing that you can be sure of is that the awareness and the evidence of the product will just expand dramatically over the next year."

262. Dr. Phillips presented PowerPoint slides detailing the company's strategy, including the need to get Acthar to its "underserved patient population" in rheumatology, pulmonology, ophthalmology, dermatology and kidney disease.

263. One graphic showed 9,000 patients were currently being treated with Acthar and that 300,000 people had "addressable but currently untreated" conditions. The slide also noted a total of 4 million Americans suffered from "Acthar indicated conditions."

264. The aggressive marketing push outlined by Mallinckrodt executives in that October 2014 investor meeting appears to have paid off: Medicare spent more than $600 million on more than 12,000 Acthar claims in 2016 – more than double the numbers from 2013, the year before Mallinckrodt's purchase of Questcor. Many of those prescriptions were made by rheumatologists, nephrologists, and neurologists – the very type of doctors Mallinckrodt executives said they planned to target in October 2014 to capture the "underserved patient population."

265. In 2018, Local 420 began paying for Acthar prescriptions for the wife of one of its members for the treatment of a rheumatic disorder which as identified by Mallinckrodt as an "underserved" area.

266. Few medical providers have come forth to blow the whistle on Mallinckrodt's tactics. One brave doctor, Dr. Megan Clowse of the Duke University School of Medicine, wrote last year that "[w]e also know from personal experience that Acthar's manufacturer is actively looking for clinical researchers open to perform more, small, open-label, nonrandomized trials of their drugs." In other words, even doctors not receptive to Mallinckrodt's marketing scheme are approached. Discovery of Mallinckrodt's records will enable Plaintiff and the Class to ferret out the chaff from the wheat, the ethical doctors from the spokes-doctors.

267. One such spokes-doctor, Dr. William Shaffer, a neurologist in Greeley, Colorado, was the highest prescriber of Acthar in 2012. He wrote only 78 prescriptions for the drug, but the prescribed Acthar cost Medicare $4,000,000.

268. Dr. Shaffer has been paid handsomely by Mallinckrodt for his loyalty to the company. The very next year, Dr. Shaffer was rewarded by being engaged by Mallinckrodt to speak as a KOL on multiple occasions, in multiple places, as part of all-expense paid trips sponsored by the company. For instance, he was flown to the east coast to conduct four speaking engagements with dozens of the doctors over the course of two days, January 24-25, 2013. He spoke in Reston and Falls Church, Virginia, and then Bethesda, Maryland.

269. But Dr. Shaffer was far from alone. He is just one of dozens of highly-compensated Mallinckrodt spokes-doctors, all important spokes in the wheel of Mallinckrodt's RICO conspiracy, as they are all connected to Mallinckrodt's self-described "HUB" and all profit as integral "spokes" in Mallinckrodt's marketing and sales scheme.

4. Leading "KOLs" for Mallinckrodt Promote for "New Indications" through a Scheme of "White Coat Marketing".

270. Mallinckrodt sought help in effectuating their scheme and conspiracy by seeking KOLs in the medical fields where Acthar was not the preferred course of treatment. Indeed, Acthar was not approved by the FDA for the long-term treatment of any disease; instead, Acthar has had a narrow indication since 1952 for the treatment of only acute exacerbations of disease and flare-ups.

271. As Express Scripts' 2018 Prior Authorization Policy acknowledged, "data and guidelines do not suggest that Acthar has a substantial role in therapy" for most of the diseases for which Mallinckrodt promotes and sells Acthar. Instead, Express Scripts found in late 2017,

as the FDA found in 2010, that "[f]urther data are needed before use in other areas [beyond IS and MS] can be recommended." *Id*. at 4 (brackets added).

272. To overcome this lack of data to support to use of Acthar to treat "new indications", and to support its off-label marketing effort, Mallinckrodt engaged KOLs strategically situated throughout the country, initially to determine whether there was a viable potential market for Acthar with neurologists, nephrologists and rheumatologists.

273. In order to cultivate KOLs for its white coat marketing scheme, Mallinckrodt directed its sales force call on select neurologists, nephrologists and rheumatologists to discuss the treatment of new indications of disease with leading practitioners in these fields, and to begin developing and sharing the data on treatment with Acthar.

274. Mallinckrodt then began "[w]orking with KOLs who have expressed interest in generating such data" to support the off-label use of Acthar to treat such "new indications". This became a "major focus" for Mallinckrodt after it acquired Questcor.

275. This new marketing initiative into off-label promotion of Acthar for "new indications" was made possible by the "success of the new Acthar pricing strategy" by which "significant funds [were] now available for the first time to support Acthar-related research" by paying "KOLs to explore areas of mutual research interest." *Id.* In other words, the profits realized by the implementation of the "new strategy" in 2007 for IS treatments made it possible for Mallinckrodt to pay doctors to serve as KOLs as part of the Mallinckrodt white coat marketing strategy into rheumatology, nephrology and other areas.

276. The practice of "white coat marketing" was identified by the Office of Inspector General (OIG) of the federal government as a potential area of fraud and abuse as early as 1991.

See, e.g., OIG Advisory Opinion No. 11-08, issued June 12, 2011, at 6 (citing 56 Fed. Reg. 35952, 35974 (July 29, 1991)). As described in Advisory Opinion No. 11-08:

> The fraud and abuse risks are compounded where, as here, a physician or other health care professional is involved in the marketing activity – a practice sometimes referred to as "white coat" marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services – especially when marketing to their patients. See, e.g., 56 Fed. Reg. 35952, 35974 (July 29, 1991). Given the nature of these relationships, when physicians or other health care professionals market items and services to their patients, patients may have difficulty distinguishing between professional medical advice and a commercial sales pitch.

5. Mallinckrodt KOLs Working for Mallinckrodt as Spokes-Doctors in Pennsylvania and Throughout the Country.

277. While it is impossible without the benefit of discovery to identify and describe the full nature and extent of Mallinckrodt's unlawful white coat marketing scheme for the off-label promotion of Acthar – as only discovery will reveal the facts that lie within Mallinckrodt's exclusive custody and control – specific examples demonstrate that the scheme was widespread in Pennsylvania and elsewhere.

a. Dr. David R. Mandel in Chardon, Ohio

278. Dr. David R. Mandel ("Dr. Mandel"), is a rheumatologist with offices located at 320 Center Street, Chardon, Ohio.

279. Public reports reveal that Dr. Mandel was regarded as a top prescriber of Acthar making up 1% of all prescriptions with 14 patients receiving Acthar.

280. According to the website sponsored by Propublica,[7] Mallinckrodt claims Dr. Mandel was only paid the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout the country:

Aug. 2013 - Dec. 2013	$16,653
Jan. 2014 - Dec. 2014	$3,077
Jan. 2015 – Dec. 2015	$3,032
Jan. 2016 – Dec. 2016	$126

281. However, in 2014, Dr. Mandel pled guilty and was sentenced to probation and paid $650,000 for causing the shipment of "misbranded" drugs.

282. Mallinckrodt has been sued by a former employee, Barry Franks. In Franks' Complaint, he details the unlawful conduct of Dr. Mandel, along with another Mallinckrodt sales representative, identified as "Smith". It is believed and therefore averred that "Smith" is actually Christopher Sender, the Mallinckrodt sales manager in charge of the Ohio area where Dr. Mandel practices.

283. As a highly compensated KOL and spokes-doctor for Mallinckrodt, Dr. Mandel actively promoted the sale of Acthar to patients and TPPs for unapproved uses and doses in order to get TPPs, like Plaintiff and the Class, to pay for Acthar at inflated prices. Specifically, Dr. Mandel promoted the sale of Acthar for RA.

[7] *See* https://projects.propublica.org/docdollars/ According to Propublica, "[p]harmaceutical and medical device companies are required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2016."

284. In promoting Acthar for unapproved uses and doses in the treatment of RA, Dr. Mandel misrepresented and deceived patients and payors about the Acthar MOA and the limited FDA approval.

285. Dr. Mandel specifically wrote to payors, after his initial prescriptions for Acthar were denied due to the prior authorization TPPs had placed on Acthar to prevent high payments for specialty drugs, especially for off label indications. Working with Mallinckrodt's HUB, UBC, however, Dr. Mandel sent letters appealing the TPP's denial decisions. Such letters were sent to UBC, to be used with TPP's, through use of the mail, including email, and wires. They contained false and misleading statements about the limited FDA approval of Acthar and its purported MOA.

286. Specifically, as to the FDA approval, Dr. Mandel would write to TPPs that Acthar was approved for specific RA indications, when it was not. As for the Acthar MOA, Dr. Mandel would write to TPPs misrepresenting that the Acthar MOs was known, when it was not. Indeed, he would provide lengthy explanations about the Acthar MOA, which explanations were not based upon any FDA approval or any FDA approved clinical studies.

287. The letters sent and other communications had between Dr. Mandel and TPPs in order to appeal the denial of Acthar were vetted by and shared with Mallinckrodt and UBC. Mallinckrodt and UBC were fully aware of Dr. Mandel's misrepresentations, and yet took no steps to stop or correct them, to the detriment of the TPPs who paid for the Acthar based upon such misrepresentations. Instead, Mallinckrodt rewarded Dr. Mandel with increasing KOL speaking engagements, for which he was well compensated.

288. Based upon the JAMA study and other evidence of Mallinckrodt's KOL program for Acthar, including the above-described example of Dr. Mandel for which specific evidence is

available, it is averred that other KOLs conducted themselves in the same manner. That is, Mallinckrodt-paid KOLs misrepresented and deceived TPPs about the MOA for Acthar and the limits of its FDA approval, in order to get TPPs to pay for Acthar for unapproved uses and doses. These false and misleading communications were routed to TPPs through UBC via facsimile.

289. Plaintiff and the Class were harmed by such conduct, either directly through the promotional effort of Mallinckrodt KOLs and MSLs, or indirectly through their intercession in the care of beneficiaries of Plaintiff and the Class through the ASAP program and otherwise.

290. Plaintiff and other clients of the Plaintiff's counsel, along with unnamed members of the Class paid the inflated prices for Acthar for indications in MS, NS, SLE and RA pursuant to the fraudulent pricing, marketing and sales scheme alleged.

291. **MANDEL PROSECUTION FOR MISBRANDING**

b. Dr. James Tumlin in Chattanooga, Tennessee and Acument's Inflated Payments for Acthar

292. In a related case filed in Tennessee state court by the same undersigned Plaintiff's counsel, the plaintiff there, Acument Global Technologies, Inc. ("Acument") has specifically pled that Mallinckrodt hired Dr. James A. Tumlin, M.D. ("Dr. Tumlin") as a leading KOL to develop supporting data using his existing patients as test subjects in a non-FDA-approved, open label clinical study.

293. Mallinckrodt also paid Dr. Tumlin to travel the country, instructing other doctors on the unapproved uses of Acthar for nephrology and soliciting such doctors to become KOLs for Mallinckrodt.

294. Mallinckrodt has paid Dr. Tumlin handsomely for such work on behalf of the company. He has been paid hundreds of thousands of dollars.

295. Dr. Tumlin is a physician who specializes in nephrology and is associated with Nephrology Associates of Chattanooga located at 2300 E. 3rd Street, Chattanooga, Tennessee. He is founder and medical director of Southeast Renal Research Institute (SERRI) since 2005. The institute was brought to Chattanooga in 2008 and merged with Nephrology Associates' Research Department.

296. As with its other KOLs, Mallinckrodt contracted with Dr. Tumlin to conduct clinical studies of his patients using Acthar to treat their NS. This engagement was not to conduct any FDA-approved clinical study. Instead, it was intended by Mallinckrodt to pay Dr. Tumlin to conduct clinical studies of his own patients by prescribing Acthar to them for unapproved uses and doses to treat their nephrotic syndrome in order to learn about the effects of Acthar on their disease and assist Mallinckrodt in developing anecdotal clinical data with which to promote Acthar's use to other nephrologists. It is believed that one such patient was a beneficiary of Acument.

297. The 2009 contracted study was titled "A Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Study of H.P. Acthar Gel (Acthar) in Treatment-Resistant Subjects with Persistent Proteinuria and Nephrotic Syndrome Due to Idiopathic Membranous Nephropathy (iMN)" (hereinafter, "Tumlin 2009 Randomized Study"). It is believed and therefore averred that Dr. Tumlin "enrolled" 15 patients for this study. While Acument's beneficiary had iMN, it is unknown whether Acument's beneficiary was included among the 15 patients Dr. Tumlin treated with Acthar as part of this contracted study. Only discovery in these cases will reveal the truth.

298. However, it is known Dr. Tumlin did not charge either the beneficiary or Acument for the Acthar he prescribed in 2011. Instead, it is believed and therefore averred that

Mallinckrodt provided the drug for free in order that Dr. Tumlin could develop data to assist in its marketing and sales of Acthar to other nephrologists.

299. Dr. Tumlin's work on behalf of Mallinckrodt became a centerpiece of its marketing plan for nephrologists, not just in Tennessee, where Dr. Tumlin's practice, Southeast Renal Research Institute, was located in Chattanooga, but throughout the country, including Pennsylvania.

300. As with other KOLs, Dr. Tumlin travelled across the country on all expenses paid trips funded by Mallinckrodt to promote the use of Acthar for NS and other disease states for which there were no clinical studies to support the treatment. Instead, Dr. Tumlin cited to other doctors his own anecdotal experience with his patients, about which he published in two papers, the Tumlin 2001 Study and the Tumlin 2013 Pilot Study.

301. While it is not yet known the total dollars Mallinckrodt paid Dr. Tumlin for these two "studies" which led to published articles, those monies were only part of Dr. Tumlin's compensation for working for Mallinckrodt.

302. For instance, Dr. Tumlin conducted a third study titled "Safety and Efficacy of Acthar Gel on Albuminuria and Urinary Transforming Growth Factor Excretion in Type II Insulin Requiring Diabetics with Nephrotic Range Proteinuria: A Pilot Study". Mallinckrodt paid Dr. Tumlin for that study.

303. In its prior authorization update released in 2018 – 9 years after Mallinckrodt began white coat marketing of Acthar through KOLs like Drs. Mandel and Tumlin– Express Scripts stated that Acthar should not have been "recommended for approval" by any doctor, including Dr. Tumlin, for treatment of iMN in patients.

304. In fact, Express Scripts cited Dr. Tumlin's 2 published papers sponsored and paid for by Mallinckrodt: the Tumlin 2011 Study and the Tumlin 2013 Pilot Study,[8] in concluding that "very limited data in nephrotic syndrome have studied the use of Acthar, in patients with diagnoses including idiopathic membranous nephropathy (iMN)…".

305. Mallinckrodt MSLs and sales representatives used Dr. Tumlin's open label studies to promote the sale of Acthar for off-label uses and doses. Similarly, UBC was trained with Dr. Tumlin's studies and used them in discussing the use of Acthar for unapproved uses and doses with patients, providers and TPPs.

306. According to the website sponsored by Propublica,[9] Dr. Tumlin was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout the country, apart from the monies he has earned conducting "clinical studies" of his patients:

Aug. 2013 - Dec. 2013	$15,318
Jan. 2014 - Dec. 2014	$27,733
Jan. 2015 – Dec. 2015	$28,839
Jan. 2016 – Dec. 2016	$50,840

[8] Bomback AS, Tumlin JA, Baranaski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. *Drug Des Devel Ther*. 2011; 5:147-153 ("Tumlin 2011 Study").

[9] *See* https://projects.propublica.org/docdollars/ According to Propublica, "[p]harmaceutical and medical device companies are required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2016."

307. On multiple occasions, Dr. Tumlin was paid twice by Mallinckrodt for the same services and reimbursements, in an obvious effort to overpay Dr. Tumlin for his "consulting" activities.

308. For instance, on May 23, 2016, Propublica reports that Dr. Tumlin received two payments from Mallinckrodt for "promotional speaking" in the amount of $3,400 each. He also received two equal payments of $2,050 for "promotional speaking" July 2, 2015.

309. On June 17, 2015, Mallinckrodt paid Dr. Tumlin the following sums for "travel and lodging" for just one day: $537, $529, $393, $393, $276, $87, $50, $50, $30, $30 and $22.

310. Based on the Propublica information, it is believed that Dr. Tumlin travelled the country for Mallinckrodt to promote Acthar use in nephrology. Mallinckrodt paid with substantial "honoraria" paid, totaling up to $5,000 at time, for his time and effort.

311. The specific dates, locations and payments relating to these Dr. Tumlin's consulting for Mallinckrodt as a leading KOL lies within the exclusive control of Mallinckrodt and Dr. Tumlin, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

c. Dr. Gary Clauser in Allentown, Pennsylvania And IUOE Local 542's Inflated Payments for Acthar

312. Gary Clauser, M.D. is a board-certified neurology specialist in the Lehigh Valley Physician Group (LVPG) with offices located at 1250 S. Cedar Crest Boulevard, Suite 405, Allentown, Pennsylvania. LVPG has additional offices located in Bethlehem and Palmer Township, Pennsylvania.

313. In July 2011, Dr. Clauser treated a patient covered by the International Union of Operating Engineers Local 542 ("IUOE Local 542") located in Fort Washington, Pennsylvania. IUOE Local 542 has sued Mallinckrodt individually in Pennsylvania state court. Earlier this

year, the Court of Common Pleas of Montgomery County denied Mallinckrodt's Preliminary Objections seeking to have the case dismissed. Since that time, the case has been proceeding through discovery.

314. Because of the marketing and sales efforts by Mallinckrodt's sales representatives, including Art Veno, Dr. Clauser utilized the Acthar Start Form with his patients, including the IUOE Local 542 patient treated with Acthar. As a result, UBC coordinated the payment for Acthar by IUOE Local 542 on behalf of Mallinckrodt at the inflated AWP price set by Mallinckrodt. As a result, IUOE Local 542 and its beneficiary were harmed by the scheme and conspiracy of Defendants through their direct participation in the ASAP program.

315. Dr. Clauser has treated multiple patients in Pennsylvania with Acthar. It is believed and therefore averred that such patients and their TPPS were subjected to and harmed by the scheme and conspiracy allege herein by Dr. Clauser's role as a highly paid KOL for Mallinckrodt, and his utilization of Acthar Start Forms with his patients. Dr. Clauser has treated patients with Acthar on at least the following dates for the identified conditions: June 9, 2014 (MS); September 10, 2014 (MS); September 12, 2014 (MS); October 9, 2014 (MS); October 15, 2014 (MS); February 24, 2015 (MS); April 20, 2015 (MS); June 3, 2015 (MS); and June 8, 2015 (MS).

316. Dr. Clauser prescribed Acthar for an IUOE Local 542 beneficiary, and charged the inflated AWP-based price as set by Mallinckrodt by submitting the prescription through IUOE Local 542's PBM, Express Scripts. IUOE Local 542 paid the AWP-based price charged.

317. Specifically, Dr. Clauser prescribed an unapproved 5-day dose of Acthar to treat a patient with MS, who was also a beneficiary of IUOE Local 542. Dr. Clauser filled out an

Acthar Start Form on June 29, 2011, listing "80 units/day x 5 days" for MS, and faxed the form to UBC to obtain coverage and payment from IUOE Local 542, which it did.

318. Dr. Clauser held a meeting with Mallinckrodt in his office in Allentown on Tuesday, January 8, 2013. Also in attendance were his employees, nurse practitioner Jean Bakke-Cain and registered nurse Grace Connelly.

319. The meeting was arranged by Mallinckrodt's sales representative for the Lehigh Valley, Art Veno. Also invited to attend was one of Mallinckrodt's top 10 KOLs in the country, Dr. Ruwani Gunawardane, a neurologist from Fulton, Maryland. While it is unknown what was said at the meeting, based on the express goals of the KOL program, it is likely that Dr. Gunawardane was brought from Maryland to Allentown to further train Dr. Clauser in the "art" of being a top Mallinckrodt KOL and spokes-doctor. It is believed and therefore averred Dr. Gunawardane also taught Dr. Clauser about the off-label uses and doses of Acthar for the treatment of his patients, including for the treatment of MS. Dr. Gunawardane specifically thanked Dr. Clauser and his staff at Lehigh Neurology about "perspectives on MS relapses and Acthar."

320. Only discovery will reveal if Dr. Gunawardane has been paid more than a consulting fee, honoraria and travel expenses, such as whether she has been paid additional monies based on the Acthar sales generated by Dr. Clauser in the wake of her visit to him. Such a "pyramid scheme" would perhaps explain how Dr. Gunawardane has been able to generate more than $100,000 a year working for Mallinckrodt as a KOL, in addition to maintaining a healthcare practice in Maryland.

321. According to ProPublica, Dr. Gunawardane has been paid a staggering $1,111,326 as a paid consultant to drug companies, $332,000 of which was paid by

Mallinckrodt. She is among the top eight largest prescribers of Acthar in the country, and is among the highest paid of Mallinckrodt's KOLs.

322. Specifically, according to CNN, Dr. Gunawardane "received 502 payments worth $332,393.36 -- nearly half was compensation for services, about a third was honoraria, about a sixth was for travel and lodging, and the rest was for consulting, education and food and beverage. Gunawardane filed 38 claims resulting in $1,329,002.84 in Medicare coverage."10 Dr. Gunawardane declined to comment when confronted by CNN. Id.

323. Dr. Clauser became a Mallinckrodt "spokes-doctor" and KOL after the January 8, 2013 meeting with Mallinckrodt and Dr. Gunawardane. Dr. Clauser has been a highly KOL for Mallinckrodt for years.

324. According to Propublica, which has only published data since the second half of 2013, Dr. Clauser was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in promoting the sale of Acthar to other doctors throughout Pennsylvania and New Jersey:

Aug. 2013 - Dec. 2013	$9,124
Jan. 2014 - Dec. 2014	$26,959
Jan. 2015 – Dec. 2015	$8,727
Jan. 2016 – Nov. 2016	$18,286

[10] https://www.cnn.com/2018/06/29/health/acthar-mallinckrodt-medicare-claims-doctor-payments/index.html

325. In the first half of 2013 alone, since the meeting with Dr. Gunawardane, Dr. Clauser served as a Mallinckrodt KOL on at least the following occasions in the following places:

January 18, 2013	Wilkes Barre, PA
March 22, 2013	East Norriton, PA
April16, 2013	Bridgewater, NJ
April 18, 2013	Sellersville, PA
April 29, 2013	Manhattan, NY
May 14, 2013	Brooklyn, NY
May 21, 2013	King of Prussia, PA
June 26, 2013	Brooklyn, NY
August 1, 2013	Center Valley, PA

326. On multiple occasions, Dr. Clauser was paid twice by Mallinckrodt for the same services and reimbursements, in an obvious kickback to the doctor.

327. Based on the Propublica information, Mallinckrodt paid Dr. Clauser substantial "honoraria" and "consulting" fees, totaling up to at least $59,423, for his time and effort.

328. The specific dates, locations and payments relating to Dr. Clauser's consulting for Mallinckrodt as a KOL lies within the exclusive control of Mallinckrodt and Dr. Clauser, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

d. Dr. Steven Urbaniak in Langhorne, Pennsylvania And IUOE Local 542's Inflated Payments for Acthar

329. Steven Urbaniak, DO. is a board-certified neurologist with Oxford Neurology, LLC located at 940 Town Center Drive, Suite F50, Langhorne, Pennsylvania. Dr. Urbaniak is also on staff at St. Mary Medical Center in Pennsylvania.

330. Beginning in March 2013, Dr. Urbaniak treated a patient covered by IUOE Local 542. Dr. Urbaniak prescribed Acthar for the patient, and charged the inflated AWP-based price

as set by Mallinckrodt by submitting the prescription through IUOE's PBM, Express Scripts. IUOE Local 542 paid the AWP-based price charged.

331. Because of the marketing and sales efforts by Mallinckrodt's sales representatives, including Stacyann Clancy, Dr. Urbaniak utilized the Acthar Start Form with his patients, including the IUOE Local 542 patient treated with Acthar. As a result, UBC coordinated the payment for Acthar by IUOE Local 542 at the inflated AWP prices set by Mallinckrodt. As a result, IUOE Local 542 and its beneficiaries were harmed by the scheme and conspiracy of Defendants through their direct participation in the ASAP Program.

332. Specifically, it is believed and therefore averred that Dr. Urbaniak prescribed an unapproved 5-day dose of Acthar to treat MS in a beneficiary of IUOE Local 542, with the direct involvement and assistance of Mallinckrodt and UBC in securing payment at the inflated AWP for Acthar and IUOE Local 542.

333. Dr. Urbaniak has treated multiple patients in Pennsylvania with Acthar. It is believed and therefore averred that such patients and their TPPS were subjected to and harmed by the scheme and conspiracy alleged here in by Dr. Urbaniak's role as a highly-paid KOL for Mallinckrodt, and his utilization of Acthar Start Forms with his patients. Dr. Urbaniak has treated patients with Acthar for the treatment of MS and MS relapses on at least the following occasions: July 22,2014; October 6, 2014; October 28, 2014 and December 19, 2014.

334. Stacyann Clancy is specifically identified by Relator Strunck and Pratta as having engaged in the unlawful conduct alleged in this case. *See* Struck and Pratt Cmplt, at ¶¶ 133-134.

335. Dr. Urbaniak held a meeting in his office in Langhorne on Tuesday, January 8, 2013. Also, in attendance was another doctor by the same last name, Kathy Urbaniak, M.D. At least 8 other people from Oxford Neurology also attended.

336. The meeting was arranged by Questcor's sales representative, Stacyann Clancy, for a discussion with Mallinckrodt leading KOL, Dr. Ruwani Gunawardane.

337. While it is unknown what was specifically discussed at the 2013 meeting, it is known that Dr. Gunawardane presented on the topic of "MS Relapses and the MCR System." Dr. Urbaniak has been a KOL for Mallinckrodt for years.

338. According to Propublica, Dr. Urbaniak was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout Pennsylvania:

Aug. 2013 - Dec. 2013	$10,241
Jan. 2014 - Dec. 2014	$3,815
Jan. 2015 – Dec. 2015	$2,010
Jan. 2016 – Nov. 2016	$107

339. Since the meeting with Dr. Gunawardane, Dr. Urbaniak served as a Mallinckrodt KOL on the following occasions in the following places:

March 13, 2013	New Hope, PA
May 30, 2013	Warrington, PA
July 11, 2013	Philadelphia, PA

340. Based on the Propublica information, Mallinckrodt paid with substantial "honoraria" and "consulting" fees, totaling up to $59,423, for his time and effort.

341. The specific dates, locations and payments relating to these Dr. Urbaniak's consulting for Mallinckrodt as a KOL lies within the exclusive control of Mallinckrodt and Dr.

Urbaniak, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

e. Dr. Irene Greenhouse Jamison, Pennsylvania And IUOE Local 542's Inflated Payments for Acthar

342. Irene Greenhouse, M.D. is a board-certified neurology specialist with offices located at 2370 York Road, Jamison, Pennsylvania.

343. In July 2014, July 2015 and throughout 2017, Dr. Greenhouse treated a patient covered by IUOE Local 542.

344. Dr. Greenhouse prescribed Acthar for an IUOE Local 542 beneficiary, and charged the inflated AWP-based price as set by Mallinckrodt and as charged by UBC by filling out multiple Acthar Start Forms and submitting them to UBC via facsimile in order to engaged the ASAP program established by Defendants as part of their scheme to defraud TPPs. On the forms, Dr. Greenhouse listed the disease state as "multiple sclerosis", but claimed each time that the Acthar treatment was allegedly for an MS exacerbation, in order to try to bring the prescription within the Acthar approved label. However, as set forth below, there was insufficient evidence presented by Dr. Greenhouse to support her claim of an MS exacerbation.

345. Further, each time, Dr. Greenhouse prescribed an unapproved 5-day dose of Acthar to treat the MS. As described above by Relators Strunck and Pratta, this put the patient at unnecessary risk, in view of other available, safe and effective, and even cheaper medicines. Specifically, this particular patient was trying to become pregnant. Acthar's label specifically warns that "H.P.Acthar has been shown to have an embryocidal effect. There are no adequate and well-controlled studies in pregnant women. H.P.Acthar should be use during pregnancy only if the potential benefit justifies the potential risk to the fetus."

346. It is believed that Dr. Greenhouse never stated to UBC, or IUOE Local 542, in her submissions through the ASAP that she had made any determination that "the potential benefit justifies the potential risk to the fetus."

347. It is believed and therefore averred that at some point prior to 2013, Dr. Greenhouse was trained in the "art" of being a top Mallinckrodt KOL and spokes-doctor by someone at Mallinckrodt, and likely another as-yet-unknown KOL.

348. Only discovery will reveal if Dr. Gunawardane was that KOL, as she has trained two other area Pennsylvania neurologists, Dr. Clauser and Dr. Urbaniak, both of whom treated IUOE beneficiaries suffering from MS with Acthar.

349. It is known that Dr. Greenhouse has been paid thousands of dollars acting as a Mallinckrodt KOL.

350. According to Propublica, which has only published data since the second half of 2013, Dr. Greenhouse was paid by Mallinckrodt at least the following disclosed sums for her promotional activity on behalf of Mallinckrodt in promoting the sale of Acthar to other doctors:

Aug. 2013 - Dec. 2013	$35,705
Jan. 2014 - Dec. 2014	$48,878
Jan. 2015 – Dec. 2015	$50,278
Jan. 2016 – Nov. 2016	$37,250

351. The specific dates, locations and payments relating to these Dr. Greenhouse's consulting for Mallinckrodt as a KOL lies within the exclusive control of Mallinckrodt and Dr. Greenhouse, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

352. It is known that Dr. Greenhouse has been prescribing Acthar since at least 2012, when Mallinckrodt and UBC were rolling out their schemes to promote Acthar for unapproved uses and doses in the treatment of lupus. For instance, on October 3, 2012, while Dr. Greenhouse was working for Meadowbrook Neurology on Huntingdon Pike in Huntingdon Valley, Pennsylvania she prescribed Acthar for the treatment of lupus in a patient.

353. Critically, Dr. Greenhouse asked UBC to have Mallinckrodt send her an MSL. UBC's note states "Please have a Rheum msl follow up." In other words, Defendants utilized Mallinckrodt's MSLs in their dealings with Dr. Greenhouse.

i. The case of "Patient A"

354. In this case, there is at least one example of a patient's safety being potentially put at risk, contrary to the approved Acthar label, as a direct and proximate result of the Defendants' unlawful conduct alleged herein.

355. A beneficiary of IUOE Local 542, known a "Patient A" to protect the patient's identity and HIPAA rights,11 has been treated by Dr. Irene Greenhouse of Jamison, Pennsylvania for MS. As explained below, Dr. Greenhouse is a Mallinckrodt KOL. Dr Greenhouse has been paid tens of thousands of dollars by Mallinckrodt to act as a "spokes-doctor" for the company for years. Specifically, on information and belief, Dr. Greenhouse has been paid by Mallinckrodt to speak to other doctors about her experience in prescribing Acthar for the treatment of MS exacerbations, including treatment with an unapproved, 5-day dosing regimen, like she has prescribed for her MS patients for years.

[11] Defendants are fully aware of the identity of Patient A, as they alone possess and control the documents from which the above facts were gleaned. They only way Plaintiff and its counsel will be able to glean such facts about Local 420's own patient, and the patients of other TPPs in the Class, will be through discovery in this case.

356. In 2017, Dr. Greenhouse prescribed an unapproved, 5-day dosing regimen of Acthar for the treatment of a supposed MS exacerbation in Patient A. She did this on multiple occasions in 2017. Dr. Greenhouse had previously prescribed the same unapproved, 5-day dosing regimen for Acthar to Patient A for a supposed MS exacerbation in the years 2014 and 2015, while Mallinckrodt and UBC were actively promoting Acthar for such unapproved dose. Specifically, she prescribed Acthar to Patient A for a 5-day dose in July of 2014 and July of 2015.

357. Both times, IUOE Local 542 was charged the inflated, AWP-based price for Acthar by UBC and Mallinckrodt, despite the fact the Acthar was not approved for such a treatment.

358. Both times, IUOE Local 542 paid a discounted price off the AWP, pursuant to its plan with Express Scripts. These amounts were $32,180.68 for the July 2014 prescription, and $34,653.95 for the July 2015 prescription, respectively.

359. The inflated AWPs at the time for Acthar were $37,951.20 and $40,840.80, respectively.

360. Patient A paid co-pays of $40.00 and $20.00 for these administrations, respectively. However, Patient A was not charged a co-pay for the 2017 prescriptions. Instead, Patient A was transferred to Mallinckrodt's Patient Assistance Program ("PAP"), which PAP was run by UBC. Patient A was approved by UBC and Mallinckrodt for long-term PAP, meaning Patient A was not required to pay any co-pay for any present or future Acthar prescriptions. Thus, IUOE Local 542 was directly and proximately harmed by the Defendants' conduct in running the PAP as described below, as part of the overall Marketing Enterprise.

361. The FDA-approved label for Acthar states that Acthar may be prescribed for an MS exacerbation. It is unclear that Patient A ever suffered from an MS exacerbation. Such conclusion was questioned by the medical professionals who reviewed Dr. Greenhouse's prescription, and denied such claim.

362. As set forth above, Acthar is only approved to treat MS exacerbations.

363. It is also unclear whether Patient A was treated with approved generic methylprednisolone, or other approved treatments, prior to being prescribed Acthar, as required.

364. In the 2015 prescription, Dr. Greenhouse wrote on the Acthar Start Form that Patient A was given Solu-Medrol IV "2 yrs ago" and that it "failed" then. In other words, in 2013, Patient A was apparently prescribed Solu-Medrol IV. However, she was prescribed Acthar in both 2014 and 2015 without having been prescribed Solu-Medrol or any other approved treatment for MS. Since Acthar is not a "first-line" treatment for MS, a failure of other approved medications is required. But, that was not done by Dr. Greenhouse. Instead, she referenced only an apparent 2013 prior treatment with methylprednisolone as the basis for claiming that Acthar was indicated in later years, to wit, 2014 and 2015. No FDA-approved clinical studies have been done to support such a conclusion.

365. In view of the foregoing, the 2014 and 2015 prescriptions for Acthar were off label in several respects: (1) there was no clear evidence of an MS exacerbation, as required; (2) there was no first-line treatment with an approved medication, and a failure of the same, prior to the Acthar administration, as required; (3) the dose of Acthar prescribed was for an approved, 5-day course of therapy.

366. Beyond the fact that the Acthar prescribed to Patient A in 2014 and 2015 was unapproved, IUOE Local 542 was overcharged for such prescriptions by paying an AWP-based price, as set and charged by Defendants.

367. In 2017, Patient A was prescribed Acthar for an unapproved use and dose a third time.

368. However, this time, IUOE Local 542 had put in place an independent, second level review as part of its mandatory PA. MCMC, LLC of Quincy Massachusetts independently reviews drug claim decisions made by Express Script when challenged on appeal. This was important because, after Dr. Greenhouse prescribed the Acthar to Patient A in March 2017, it was denied.

369. Dr. Greenhouse and UBC then appealed the decision. It was denied a second time.

370. When the claim was first presented in March 2017, IUOE Local 542's PBM denied the claim for the following reasons:

> Coverage is provided in situations where that the patient is unable to use high-dose intravenous (IV) corticosteroids; OR, the patient has tried high-dose corticosteroids administered IV (methylprednisolone 500 to 1,000 mg IV daily for 3 to 5 days) and experienced a severe or limiting adverse effect. Coverage cannot be authorized at this time.

371. In other words, IUOE's PBM was not presented with sufficient evidence that Patient A had been given high-dose corticosteroids, like Solu-Medrol IV, in 2017, and that such treatment failed. As a result, IUOE Local 542 coverage was denied.

372. On the second appeal, Dr. Greenhouse's Acthar prescription was denied again on April 15, 2017 by MCMC for the below stated reasons:

> Acthar is approved for treating MS relapses in patients who are unable to tolerate or have an adverse reaction to steroids. In Patient A, there is no objective

> evidence of a relapse as MRI's were reported [by Dr. Greenhouse] as "There were no lesions per my review". Objective evidence of MS relapse would be contrast enhancing lesions. [Patient A was] also not on any disease modifying therapy, and the symptoms could represent baseline untreated MS and not an exacerbation. The failure of prior steroids was also not clear, and the conversation with the provider [Dr. Greenhouse] was unable to clarify this. Therefore, the requested H.P. Acthar Unit/ML Vile does not meet Prior Authorization (PA) criteria.
>
> Furthermore, the clinical literature also does not support the use as there is no clear MS exacerbation, nor is there a clear failure or adverse reaction to steroids documented. Therefore, the requested H.P. Acthar Unit/ML Vial is not medically necessary outside of PA criteria.
>
> This determination by MCMC constitutes the final review of the services under the terms of The Plan.

373. Dr. Greenhouse prescribed the 5-day dose of Acthar to Patient A despite the fact that Patient A reported "she is trying to get pregnant". In fact, Patient A had suspended her treatment with copaxone to treat her MS because she was trying to become pregnant. The Acthar label specifically warns of potential fetal harm in patients who are pregnant.

374. The label further warns of use of Acthar in "Specific Populations" as a follows:

> **8.1 Pregnancy**
>
> Pregnancy Class C: H.P.Acthar has been shown to have an embryocidal effect. There are no adequate and well-controlled studies in pregnant women. H.P.Acthar should be use during pregnancy only if the potential benefit justifies the potential risk to the fetus.

375. Despite such clear warning in the Acthar label, Dr. Greenhouse prescribed an expensive, 5-day dose of Acthar for her "likely MS exacerbation and because she failed steroids in the past."

376. In fact, Patient A had only been prescribed steroids 4 years before the 2017 prescription, and there was no clear diagnosis of an MS exacerbation. This was expressly found by MCMC.

377. Yet, in arguing for coverage and payment by IUEO Local 542, on March 27, 2017, Dr. Greenhouse wrote a letter "to whom it may concern" in an effort to get IUOE Local 542 to reverse the PA denial. Dr. Greenhouse faxed the letter to UBC, which in turn forwarded it by use of the wires to as-yet-unknown other persons in an effort to get IUOE Local 542 to reverse its denial of coverage.

378. The letter states, in pertinent part, as follows:

> Patient A "is experiencing severe MS exacerbation and has tried and failed IV steroids. Please approve [the] Acthar Gel which is the FDA approved medication for Multiple Sclerosis Exacerbations. … Please help [Patient A] to get better by allowing [Patient A] to have the medication that is FDA approved."

379. These statements were false, misleading and deceptive statements in several respects.

380. First, as MCMC found, "there is no objective evidence of a relapse". Dr. Greenhouse's statement that Patient A "is experiencing severe MS exacerbation" was unsupported, and "the symptoms could represent baseline untreated MS and not an exacerbation", as MCMC also found.

381. Second, "the failure of prior steroids was also not clear, and the conversation with the provider [Dr. Greenhouse] was unable to clarify this." Because "[Patient A was] also not on any disease modifying therapy," as required, Dr. Greenhouse's statement that she "has tried and failed IV steroids" was at least deceptive, if not misleading, insofar as it purported to indicate that Patient A recently tried steroids in relation to the claimed 2017 MS exacerbation.

382. Finally, the FDA has not "approved" Acthar for Patient A's condition, as urged by Dr. Greenhouse.

383. The fact that Defendants coordinated the drafting and sending of a misleading and deceptive letter, by use of the mail and wires, in an effort to bypass IUOE Local 542's PA in

order to get the TPP to pay for the high-priced Acthar for an unapproved use and dose is direct evidence of their scheme and conspiracy alleged in this case.

384. On May 24, 2017, Dr. Greenhouse filled out a "Prior Authorization Form" provided by Independence Blue Cross ("IBC"), the major medical healthcare provider of Patient A. By the form, Dr. Greenhouse requested coverage for the unapproved, 5-day dose of Acthar for a supposed MS exacerbation. In response to a request for "any member information that may be useful in the decision-making process, Dr. Greenhouse misleadingly reported "my pt [patient] *has tried* and [sic] IV steroids with no relief." Emphasis added. The statement was misleading because, in plain English, "has" is the third person singular of the present tense of "have", denoting a present use of IV steroids, not the prior use 4 years ago. As before, Dr. Greenhouse was deliberately trying to convince IBC that Patient A has failed IV steroids in 2017 in order to garner approval of the off-label prescription of Acthar.

385. The blank form was faxed to Dr. Greenhouse on May 24, 2017 at 2:41p.m. Dr. Greenhouse filled out the form and then faxed it to UBC at 3:38p.m. UBC then interceded with IBC to get it to cover the Acthar based on the misleading information provided by Dr. Greenhouse.

4. Mallinckrodt's and UBC's False and Misleading Marketing About the "Mechanisms of Action" for Acthar, in Promoting the Drug for a Wide Range of Unapproved Uses and Doses, Putting Patients at Substantial Risk.

386. In addition to the lack of proven safety or efficacy for the host of uses and doses that Mallinckrodt and UBC promote Acthar in neurology, nephrology and rheumatology, and the dangerousness of Acthar for such unapproved uses and doses, Mallinckrodt and UBC do not know, and have not known since it acquired the product was acquired by Mallinckrodt in 2001,

the exact "mechanism of action" ("MOA") for Acthar. In other words, neither Mallinckrodt nor UBC know how Acthar works, even to treat the disease states for which it has been approved.

387. In view of this lack of understanding of the MOA for Acthar, the FDA has mandated the following lines be included on the Acthar label:

> **12 CLINICAL PHARMACOLOGY**
>
> **12.1 Mechanism of Action**
>
> **The mechanism of action of H.P. Acthar Gel in the treatment of infantile spasms is unknown.**

388. In 2010, in response to Mallinckrodt's request for approval of the IS indication for Acthar, the FDA expressly found that "the exact mechanism of action for specific indications, such as the treatment of infantile spasms, is not known." DDMAC Memo at 1 (emphasis added). The FDA made such finding in part due to the fact that the original FDA approval in 1952 was based upon limited clinical evaluation of patients, not any current FDA-approved clinical study standards.

389. Despite these unambiguous findings by the FDA, both Mallinckrodt and UBC misrepresent and deceive providers, patients and TPPs into prescribing, taking and paying for Acthar, respectively, for unapproved uses and doses. Mallinckrodt has repeatedly and consistently misrepresented to the public the "value" of Acthar for specific indications, including the rheumatoid disorder for which the Local 420 beneficiary was prescribed Acthar. UBC coordinates the Acthar prescription from inception to payment, answering all questions posed by providers, patients and TPPs, including questions about the MOA for Acthar and whether it works for the prescribed indication.

390. Internally, Mallinckrodt concedes that, even for IS, the "[e]xact mechanisms of action of ACTH in the treatment of infantile spasms are not fully understood."

391. Publically, however, Mallinckrodt has falsely and misleadingly promoted the sale of Acthar for the long-term treatment of MS, NS, SLE and RA, despite its limited approval for only acute exacerbations of disease.

392. Indeed, it has been part of Mallinckrodt's long-term business strategy since 2007 to promote the administration of Acthar as a maintenance medication for all indications where it is approved only for the treatment of acute episodes or exacerbations of disease.

393. Prior to the launch of the new strategy in 2007, Mallinckrodt's top executives, at best, had a "rudimentary understanding" of the Acthar MOA. Nevertheless, Mallinckrodt's top executives have routinely misrepresented the value of Acthar for the treatment of specific unapproved indications, despite the FDA's express finding that the MOA is not known.

394. For instance, Mallinckrodt's former COO Steve Carrt has admitted under oath before the FTC that "in 2006, we had only a very rudimentary understanding of either Acthar or synthetic ACTH, understanding both products evolved considerably between 2006 and the present time."

395. Since that time, Mallinckrodt's knowledge of the MOA for Acthar has remained "rudimentary" as to all the disease states for which Mallinckrodt markets and sells Acthar, including and especially those for which there has been no FDA approval.

396. This lack of understanding has not impacted Mallinckrodt's training of UBC's RS's who alone interface with the providers, patients and payors, passing on Mallinckrodt's misleading and deceptive messages about Acthar's purported uses and benefits.

397. In August 2011, when asked directly by investors about the Acthar MOA, Questcor CEO Don Bailey claimed publicly that while "Acthar is an extraction of porcine pituitaries", "it's an undisclosed composition, so that's a trade secret." In other words, he misled

the public that the company would not disclose the "undisclosed composition" of Acthar, when in actuality it was unknown. Bailey further claimed falsely that it is a barrier to entry for competitors to enter the market for ACTH drugs because "there are probably multiple active ingredients" in Acthar, and "there are multiple peptides within Acthar, and they're undisclosed." (emphasis supplied).

398. Claiming that the MOA for Acthar is "undisclosed" blatantly misrepresents that it is somehow known by Mallinckrodt, but is not being disclosed by the company because it is supposedly a "trade secret". It can only be a trade secret if it is known.

399. During that same investor conference call, CEO Bailey was questioned about the MOA for Acthar, and stated "there is actually a fair amount of confusion about the mechanism of action here." He then passed the question to Christine Clemson, Mallinckrodt MSL. Clemson falsely claimed, "[w]e now know [about Acthar's] effects in, say, MS are really relevant to its direct effect on the immune system. …So that's really the primary, direct effect of Acthar that I discuss in an MS's office. This is new information…." *Id.* (emphasis supplied).

400. As discussed below, in the case of the beneficiaries of IUOE Local 542, Mallinckrodt's and UBC's direct misrepresentations about the purported MOA of Acthar in the treatment of MS exacerbations, through their MSLs/sales representatives and RSs, respectively, led to those beneficiaries receiving unapproved, off label, 5-day dosing of Acthar, for which IUOE Local 542 was forced to pay inflated Acthar prices.

401. Both Mallinckrodt and UBC have encouraged KOLs to speak to patients and TPPs about the MOA of Acthar in order to get them to agree to prescriptions of Acthar for unapproved uses and doses.

402. For instance, in the case of Dr. Mandel, when one of his patients was denied coverage for Acthar on February 27, 2014, he faxed UBC a letter to be sued with the "Clinical Appeals Department" of Express Scripts. In the letter, Dr. Mandel falsely and misleading requested coverage for RA – not an RA exacerbation. He claimed "medical necessity" and stated "H.P. Acthar Gel is FDA approved therapy for Rheumatoid Arthritis". He then stated "Acthar has a very unique mechanism of action", and proceeded to try to explain what the FDA has mandated on the Acthar label is "unknown." This letter was used by UBC and Mallinckrodt to get coverage for the patient for RA, an unapproved use.

403. Since the time of the adoption of the new strategy in 2007, Mallinckrodt has been spending money in research to try to discover and understand the MOA of Acthar, all the while promoting the drug as safe and effective for the treatment of diseases for which it is has not been approved and for which its efficacy remains unknown, especially at the doses Defendants promote.

404. Despite its longstanding "rudimentary understanding" of the Acthar MOA, Mallinckrodt and UBC have continued to aggressively promote Acthar as both safe and effective, and valuable, for the treatment of a host of diseases, including as long-term, maintenance medication for MS, NS, SLE and RA.

405. Due to their aggressive marketing, Mallinckrodt sales representatives and MSLs, and UBC "Reimbursement Specialists" or "RSs", are questioned most often by doctors about the efficacy of Acthar and its MOA. Mallinckrodt sales representatives and MSLs, and UBC's RSs, are trained to misrepresent the truth about Acthar's MOA and its limited efficacy, and to deceive providers, patients and TPPs about the limited benefits of Acthar.

406. Because it operates Mallinckrodt's HUB for the ASAP program, these same questions are most often posed to UBC. These people are known as "Reimbursement Specialists" or "RSs", and they are assigned to each patient at the time of the Acthar Start Form submission or initial call to UBC. The RS then follows the patient's case until delivery of Acthar and payment by the TPP.

407. The UBC RS directly communicates the false and misleading messages of Mallinckrodt about Acthar, its uses and doses, including off label uses and doses, its supposed benefits in relation to other treatments, and its price and value for the price charged. They do this because they are directly trained by Mallinckrodt MSLs and other employees sent by Mallinckrodt to train all new RSs, and to update the training of existing RSs. UBC RSs are not clinical pharmacists; they have no medical degrees. They are specialists in prescription drug reimbursement. In other words, they specialize in finding ways to get high priced drugs like Acthar paid for by TPPs like Local 420.

408. Neither Mallinckrodt's nor UBC's marketing and promotion of Acthar described in this Complaint has been submitted to, reviewed by, or approved by the FDA, as required.

409. In light of that, as discussed below, the DOJ has chosen to intervene in the lawsuit brought by Qui Tam Relators Strunck, Pratta and Clark to advance the claims of these former Mallinckrodt employees challenging such marketing and sales scheme. See generally, Strunck & Pratta Complaint and U.S. Complaint filed in this Court.

5. Mallinckrodt Funds "Patient Assistance Programs" Run by UBC to Fund Patients Copays to Circumvent Patient Complaints and TPP Advance Awareness about Acthar's High Prices.

410. In the U.S. Complaint in Intervention, the government includes detailed allegations about Mallinckrodt's use and employment of free Acthar and copay assistance

through a "scheme [that] allowed the Company to continually raise Acthar's price yet market it as 'free' to patients and doctors, shifting the drug's ever-increasing cost to Medicare." Id. at ¶ 2.

411. So too, such Marketing Scheme allowed Mallinckrodt, with UBC's direct assistance and intervention in running the Mallinckrodt "Patient Assistance Program" or "PAP", to shift the high costs of Acthar to private payors, like Local 420, IUOE Local 542 and the Class of TPPs and their beneficiaries.

412. As the government alleges, "Mallinckrodt [and UBC] knew that the cost of Acthar would make it difficult to sell because there were cheaper, effective competitor drugs available to treat certain of its approved uses, namely acute exacerbations of multiple sclerosis, lupus and rheumatoid arthritis. Mallinckrodt [and UBC] intended to overcome this difficulty and did so by making the drug 'free' to patients by subsidizing their Medicare copayments. By doing so, Mallinckrodt [and UBC] could maintain the high price of Acthar to maximize [their] own sales revenues, but minimize the risk that the drug's high price would impede doctors and patients from using it." Id. at ¶ 4 (brackets added).

413. "Mallinckrodt knew that paying copay subsidies to Medicare [and private] patients was illegal. To achieve the same end indirectly, Mallinckrodt paid copay subsidies through a foundation that Mallinckrodt used as a conduit to do so. At the foundation, call the Chronic Disease Fund (now d/b/a Good Days)(collectively "CDF"), Mallinckrodt designed the supposed 'patient assistance' funds that paid copays for Acthar only and then funded them through 'donations' knowing that its money would be used on Acthar copays to the exclusion of other drugs. Mallinckrodt then sent Medicare [and private payor] patients to CDF in order to receive virtually guaranteed, Mallinckrodt-funded subsidies. The Company also obtained and used data about the number of patients at CDF, the subsidies paid to them, and the amount of

money Mallinckrodt needed to pay to keep covering Acthar copays. Mallinckrodt financed the funds accordingly." Id. at ¶ 5 (brackets added).

414. "Mallinckrodt sent patients to CDF via the Company's 'reimbursement hub' [UBC] for Acthar, called the Acthar Support and Access Program ("ASAP"). Mallinckrodt controlled ASAP, which included a call-center that received referrals for Acthar from physician offices and patients. Mallinckrodt's sales force took steps to ensure that any Acthar prescriptions were routed through ASAP so the Company could track them. After a referral came in to ASAP, as discussed in more detail [herein], ASAP [via UBC] provided patients with an 'automatic offering' of copay assistance via CDF." *Id.* at ¶ 100 (brackets added).

415. Mallinckrodt set up a specific fund with CDF titled the "MS Acute Exacerbation Fund" for which Acthar was the only listed treatment, in order to ensure that all monies "donated" by Mallinckrodt were earmarked exclusively for patients receiving Acthar. Then, all the provider, working with UBC, need to do was to list the patient's indication as an "MS Exacerbation" in order to send the patient to CDF for copay assistance with their Acthar copay. The MS Acute Exacerbation Fund had at least twice the available benefit per patient than any other program offered by CDF – at least $8,000. That was likely to ensure that any copay up to 20% would be covered.

416. As the government alleges, "Mallinckrodt, via ASAP [and the UBC HUB], referred Acthar patients to the fund regardless of whether they were using the drug for an acute exacerbation or on a long-term basis. Internally, Mallinckrodt referred to this longer-term use of Acthar in MS patients as 'pulse maintenance' or 'pulse' therapy." Id. at ¶102 (brackets added).

417. In this case, Local 420 paid the high cost of Acthar for a beneficiary with RA, while IUOE Local 542 paid the high cost of Acthar for several beneficiaries with MS. With

respect to the alleged PAP conduct, Patient A was provided long term PAP assistance for a supposed MS exacerbation, through a program run by the Chronic Disease Fund ("CDF") and funded exclusively by money provided by Mallinckrodt. UBC directed Patient A to the CDF for such PAP.

418. Plaintiff alleges that Mallinckrodt employed UBC, the HUB, to coordinate sending the patients to CDF, like Patient A. As described above, once IOUE Local 542's PA successfully denied the appeal of the coverage decision for a supposed MS exacerbation, Dr. Greenhouse, UBC and Mallinckrodt sought to circumvent that PA by referring Patient A to "Long Term PAP", as opposed to "Short Term PAP".

419. Long Term PAP is defined as "PAP support for prequalified patients that are either uninsured" – not Patient A – "or rendered underinsured such that coverage is otherwise unattainable" – not Patient A. In contrast, Short Term PAP is defined as "PAP support for Patients experiencing … Multiple Sclerosis Acute Exacerbation", supposedly Patient A according to the diagnosis of Dr. Greenhouse in 2014, 2015 and 2017.

420. If Patient A suffered from MS exacerbation, she could not have been eligible for Long Term PAP. Nevertheless, in accordance with the object of the Marketing and Pricing Schemes alleged, Patient A was referred by Defendants and Dr. Greenhouse to Long Term PAP.

421. Similar to the MS Acute Exacerbation Fund, Defendants set up additional PAP funds with CDF. One such additional fund was the "RA Exacerbation Fund". Again, the amount of the benefit was more than twice that of other funds at CDF, at least $8,000 per patient, and the only drug treatment available under the fund was Acthar. Thus, Defendants replicated the success they had with the MS fund in other disease areas, including RA.

THE QUI TAM WHISTLEBLOWER COMPLAINT AGAINST MALLINCKRODT

422. On April 30, 2019, CNN reported that the United States Department of Justice ("DOJ") had intervened in a false claims act action brought by two former employees of Mallinckrodt.

423. The intervention actually took place the month before, on March 6, 2019, but the case was sealed at the time. See Plaintiff Under Seal v. Defendant Under Seal, Civil Action No. 12-CV-0175-BMS, E.D.Pa., at Dkt. No. 55. The government's decision to intervene, a relatively rare occurrence, was done after the government conducted its own extensive investigation of the claims by the former employees and concluded that the allegations are credible.

424. The case, now known as U.S. ex. Rel. Charles Strunck and Lisa Pratta, was filed in 2012 by Charles Strunck, New York-based former Multiple Sclerosis ("MS") Sales Specialist for Questcor, and Lisa Pratta, a New Jersey-based Acthar neurology specialist for both Questcor and Mallinckrodt (collectively, the "Relators"). Strunck worked from September 2010 through August 2011, while Pratta worked from September 2010 through June 2017.

425. As reported by CNN, and as averred in their Qui Tam Complaint, the Relators allege that Mallinckrodt has engaged in a long-standing scheme to bribe doctors to prescribe Acthar at the exorbitant, inflated prices detailed herein. They claim there was a "culture" at Mallinckrodt designed to sell Acthar at all costs, from lying to the FDA to offering bribes to doctors.

426. Importantly, Mallinckrodt has not denied the allegations. Instead, Mallinckrodt claims the conduct alleged is a "legacy matter" involving Questcor and its conduct prior to Mallinckrodt's acquisition.

427. However, Relator Pratta, who worked at both Questcor and Mallinckrodt after the 2014 acquisition, has alleged that the conduct continues at Mallinckrodt.

428. In a conference call with investors held May 7, 2019, CEO Mark Trudeau publicly stated that the company has reserved for the settlement of the Relators' case and is actively pursuing settlement which he stated is "likely to resolve sooner than later".

429. The conduct alleged by Relators involved kickbacks to doctors in the form of free Acthar, as well as active concealment by Mallinckrodt of the conduct for years.

430. For this reason, Local 420 did not know and could not have known about such unlawful conduct until the earliest date of April 30, 2019. As a result, Plaintiff's claims stated herein premised upon the unlawful conduct revealed by the Relators' case are timely.

431. Plaintiff had no way of knowing that Mallinckrodt was paying doctors thousands of dollars to prescribe Acthar to their patients.

432. The kickback scheme involved the promotion of Acthar to treat disease states for which Acthar was not the "gold standard", as in the case of IS, and for treatments that were not covered by the Acthar label.

433. For instance, Acthar is approved to treat acute exacerbations of disease. But the scheme uncovered by Relators involved widespread promotion of Acthar for the long-term treatment of disease as a maintenance medication.

434. Further, the scheme uncovered that Mallinckrodt sales representatives and MSLs were trained to promote unapproved doses of Acthar. For instance, in the treatment of MS exacerbations, Acthar is not approved by the FDA for 5-day dosing.

435. In the case of Local 420's beneficiary, the patient has been prescribed Acthar for years to treat a rheumatic disorder, not an RA exacerbation. As a result of Mallinckrodt's

promotional effort, instead of treating Local 420's beneficiary for an acute exacerbation, or flare-up, the patient has been given four prescriptions over the course of two months, forcing Local 420 to pay over one-hundred and fifty thousand dollars for Acthar.

436. In the case of IUOE Local 542, several beneficiaries have been treated by KOLs cultivated by Mallinckrodt to promote unapproved 5-day dosing for MS exacerbations. These prescriptions have cost IUOE Local 542 hundreds of thousands of dollars in expenditures for unapproved treatments which, in the case of Patient A, potentially put the patient at risk for a problem pregnancy.

437. The conduct revealed by the Relators goes to the manner in which Mallinckrodt was able to convince doctors to prescribe the high-priced Acthar, after the Defendant' conspired and agreed to raise the prices and maintain the prices at artificial levels, and to promote the sale of Acthar to such high prices through highly paid KOLs. The conduct involved systematically promoting and marketing Acthar for unapproved, off-label uses and doses, including the rheumatic disorder for which the Local 420 beneficiary has been prescribed Acthar.

438. The scheme involved compensating sales representatives thousands of dollars to promote the sale of Acthar for unapproved uses and doses, to benefit Mallinckrodt and the sales reps. Sales representatives have been paid tens of thousands of dollars for such promotional efforts. As detailed in the Relators' Qui Tam Complaint, one sales representative was paid a $124,000 bonus in the second quarter of 2011, including $75,000 for just one month. Others received bonuses of $110,000 and $80,000 in the same period.

439. The compensation of sales reps was directly tied to sales growth, a growth that was possible by expanding the approved uses for Acthar which had a narrow, limited market of patients.

440. Mallinckrodt employed a team of MSLs, like Sagar Shah, who were directed by Nikki Mutschler to join with sales specialists, like Strunck and Pratta to promote the sale of Acthar for unapproved uses. The Relators have identified the sales representatives who detailed the doctors of patients covered by IUOE Local 542, like Stacyann Clancy.

441. To hide the fact that the promotional effort was for unapproved, off-label uses, Mallinckrodt referred to such uses as "new indications."

442. The sales of Acthar for these "new indications" became a primary focus for Mallinckrodt, as it strived to grow its revenue to the more than $1 billion in sales it achieves each year for Acthar alone.

443. Mallinckrodt achieved such exponential growth, despite the price increases detailed herein, by providing valuable remunerations to doctors to induce and encourage them to prescribe Acthar for unapproved uses and doses.

444. As the Relators' Qui Tam Complaint reveals, and as Local 420 alleges herein, Mallinckrodt engaged in such conduct in violation of the consumer fraud laws by providing secret kickbacks to doctors throughout the country, including Pennsylvania, to get them to prescribe Acthar at exorbitant prices, which Local 420 has been forced to pay. That is why Plaintiff seeks declaratory and injunctive relief against Mallinckrodt to end such practices.

CLASS ACTION ALLEGATIONS

445. Local 420 brings this action pursuant to Rules 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and other similarly-situated persons and entities, and their beneficiaries, in Pennsylvania and throughout the country. The proposed Class includes:

> All third-party payors and their beneficiaries in the United States and its Territories that paid for Acthar from August 2007 through

the present for any unapproved indication or dose.

446. Excluded from the above Class are: (a) Mallinckrodt and any entity in which Mallinckrodt has a controlling interest, and its legal representatives, offices, directors, assignees and successors, (b) any co-conspirators with Mallinckrodt, and (c) any government payor, including Medicare, Medicaid and/or Tricare.

Numerosity

447. The proposed Class consists of thousands of private payors in the proposed Class located throughout Pennsylvania and the United States, based on the fact that Mallinckrodt has sold thousands of vials of Acthar in each quarter over the last few years alone. Thus, the Class is so numerous that joinder of all of its members is impractical.

448. Despite the size of the Class, its members are easily identifiable and ascertainable, as each patient has been required by Mallinckrodt since 2007 to fill out an Acthar Start Form as part of the ASAP. As a result, the records needed to identify the members of the Class, and the payments made by TPPs and their beneficiaries in the Class, are in the hands of the Mallinckrodt and/or its agents.

Typicality

449. Local 420's claims are typical of the claims of the Class, in that the representative Plaintiff is an entity who, like other Class Members, paid for Acthar at the inflated prices due to the unlawful conduct of Mallinckrodt. Local 420, like all similarly-situated Class members, has been damaged and has sustained economic injuries in the form of overcharges by the misconduct of Mallinckrodt, because it paid higher prices than it would have paid absent Mallinckrodt's improper actions.

Adequacy of Representation

450. Local 420 can and will fairly and adequately represent and protect the interests of the Class. Plaintiff has no interest that conflicts with or is antagonistic to the interests of the Class.

451. Local 420 is represented by counsel who are experienced and competent in the prosecution of complex actions, including consumer fraud class actions.

Commonality

452. The factual and legal bases for Mallinckrodt's misconduct are common to Class members and represent a common thread of consumer fraud resulting in injury to Plaintiff and the Class. Common questions of law and fact in this case include, but are not limited to, the following:

a. whether Mallinckrodt engaged in the unlawful marketing and sales scheme alleged;

b. whether Mallinckrodt engaged physicians as "spoke-doctors" in the scheme involving KOLs alleged;

c. whether Mallinckrodt artificially inflated the prices of Acthar;

d. whether Plaintiff and the Class have been overcharged and thus damaged by paying artificially inflated prices for Acthar as a result of Mallinckrodt's unlawful conduct;

e. whether Mallinckrodt engaged in the conduct involving PAPs and the payment of patients copays;

f. whether Mallinckrodt engaged in conduct in violation of RICO;

g. whether Mallinckrodt engaged in conduct in violation of the consumer fraud laws of Pennsylvania and other states;

h. whether Mallinckrodt has been unjustly enriched by its unlawful conduct;

i. whether Mallinckrodt negligently misrepresented Acthar to Plaintiff and the Class;

j. whether Mallinckrodt engaged in a conspiracy and/or aided and abetted others in deceiving Plaintiff and the Class about Acthar and Acthar pricing, and concealing the truth about its unlawful conduct;

k. whether Mallinckrodt is liable to Plaintiff and the Class for statutory damages for conduct actionable under the consumer fraud laws of Pennsylvania and other states;

l. whether Plaintiff and members of the Class are entitled to declaratory and injunctive relief as to Mallinckrodt's conduct;

m. whether Plaintiff and members of the Class are entitled to compensatory damages, and, if so, the nature of such damages;

n. whether Plaintiff and members of the Class are entitled to statutory damages, including treble damages;

o. the proper measure of damages; and

p. whether Plaintiff and members of the Class are entitled to an award of punitive damages, reasonable attorneys' fees, prejudgment interest, post-judgment interest, costs of suit, and other appropriate relief under the circumstances of this case.

Predominance

453. These common questions of law and fact predominate over questions, if any, that may affect only individual members because Mallinckrodt has acted and refused to act on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Mallinckrodt's unfair and deceptive conduct alleged herein.

Superiority

454. A class action is superior to any other available method for the fair and efficient adjudication of this controversy in that, among other things, such treatment will permit a large number of similarly-situated persons and entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender.

455. The prosecution of separate actions by individual members of the Plaintiff Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class. These adjudications would establish incompatible standards of conduct for Mallinckrodt which would, as a practical matter, be disparities of the claims of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

456. Mallinckrodt has acted or refused to act on grounds generally applicable to all members of the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

457. Accordingly, class certification is appropriate under Rule 23(b)(1)(A), 23(b)(1)(B), 23(b)(2) and 23(b)(3).

FORMATION OF THE UNLAWFUL ACTHAR MARKETING ENTERPRISE

458. Beginning in 2007 and continuing to the present, each Defendant implemented a marketing and promotion campaign by combining its own respective significant personnel and financial resources with peer-influencing physicians (known as KOLs) through which Defendants (i) falsely and deceptively oversold the safety and efficacy of Acthar, (ii) failed to adequately warn of, and affirmatively misled the medical community regarding the risks, benefits and value of Acthar and (iii) unlawfully promoted Acthar for usage in populations for which it had not received FDA approval and for which the safety and efficacy had not been established through adequate clinical evidence. This association-in-fact created by Defendants is denominated in this Complaint as the Acthar Marketing Enterprise. Defendants and their associated participants established the Acthar Marketing Enterprise to accomplish the common goal of causing increased prescribing activity of Mallinckrodt's Acthar for off-label uses and

doses for which Acthar was not proven to be safe, effective or useful. The scheme was accomplished through fraudulent, or false and deceptive, claims of efficacy and safety, medical usefulness, and for unlawful, off-label purposes.

459. First, to execute their Acthar Marketing Enterprise successfully, each Defendant had to create a parallel marketing structure that appeared independent from the ordinary promotion forces – they each did so both to avoid federal regulations concerning off-label promotion and to create the façade of independence behind the misleading message of safety, efficacy and non-indicated usage they each wished to promote. Defendants targeted primarily speaking events, seminars, continuing medical education ("CME") events as well as other physician gatherings. Defendants worked with and paid leading KOLS to create content for such speaking events that misrepresented the safety, efficacy, and usefulness of Acthar for off-label uses, and paid these KOLs to deliver the disguised promotional messages to unsuspecting physician attendees.

460. The goal of the Acthar Marketing Enterprise was intentionally complementary and mutually reinforcing. The Defendants' Acthar Marketing Enterprise was succeeded in distorting and polluting the medical discourse and medical literature surrounding Acthar to such a degree that physicians and patients were rendered incapable of making objective and informed decisions concerning the appropriateness of Acthar for off-label and label-expanding usage.

A. FORMATION OF THE ILLEGAL ACTHAR MARKETING ENTERPRISE

461. Defendants' Acthar Marketing Enterprise centered on hosting numerous events where KOL doctors rained and/or approved by Defendants would falsely oversell the efficacy and safety of Acthar and would provide favorable information on the off-label use of Acthar, often under conditions where physicians would be compensated for attending the presentation.

Mallinckrodt funded and continues to fund scores of such events between approximately 2007 to present.

462. The Acthar Marketing Enterprise employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy of Acthar for a variety of off-label uses; including 5-day dosing for MS exacerbations; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Acthar for both approved indications and for a variety of off-label uses and doses; (c) deliberately concealing negative findings or the absence of positive findings relating to the off-label uses of Acthar; (d) wrongfully and illegally compensating physicians for causing the prescribing of Acthar; (e) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Acthar for both on-label and off-label uses, and then disseminating copies of such studies by the thousands to the medical community as part of their marketing; (f) intentionally misrepresenting and concealing Defendants' role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Acthar to off-label markets; and (g) intentionally misrepresenting and concealing the financial ties between Defendants and other participants in the Acthar Marketing Enterprise.

463. Defendants' scheme reaped significant financial gain. From 2007 to present, Defendants revenues from the sale of Acthar soared into the millions and billions of dollars. Eventually, as a result of each Defendants' Acthar Marketing Enterprise efforts and unbeknownst to the Plaintiff and Class Member TPPS, the vast majority of Acthar prescriptions were for off-label uses. Sales of each drug have grown at a significant rate each year. Currently, Acthar represents over $1 billion in revenue to Mallinckrodt.

464. All of the participants in Defendants Acthar Marketing Enterprise associated with the respective Defendants with the common purpose of aiding them in marketing Acthar for off-label uses and to achieve "market expansion" of these uses. Each of the participants received substantial revenue or other consideration from each Defendant for their efforts in the scheme to promote Acthar off-label. The more successful these marketing events were, the more events were would be in the future and the more fees and revenues each of the participants would receive for participating in the events. For these reasons, all of the participants knowingly and willingly agreed to assist each of the Defendants in their off-label promotion of Acthar, notwithstanding the fact that such a promotional campaign required the systematic repetition of false and misleading statements to, and the commercial bribery (through kickbacks) of hundreds of physicians throughout Pennsylvania and the United States, and that the promotion of Acthar for off-label indications by Defendants was illegal.

465. Each Defendant exercised control over and participated in the Acthar Marketing Enterprise. Each Defendant compensated the other participants for their efforts, and controlled the money flow to the participating physicians. Defendants each closely monitored all activities and events to ensure the expected representations and marketing messages related to the off-label uses of Acthar were made to physicians attending the events. Following uh events, each Defendant tracked attending physicians' prescribing habits to ensure that the messaging was successful in causing prescribing activity for Acthar.

1. Role of Physicians in the Acthar Marketing Enterprise.

466. One of the principal strategies pursued by all Defendants in their Acthar marketing Enterprise was to target key physicians to serve as "thought leaders", or KOLs. These doctors promoted Acthar to their peers through peer selling programs by (i) touting Acthar's

supposed off-label uses; (ii) claiming that Acthar was being widely u sed by other physicians for off-label uses; and (iii) claiming that they were privy to the latest clinical data that had not been released yet, but which would support off-label use.

467. To lure physicians to participate in the Acthar Marketing Enterprise, Mallinckrodt sales representatives and MSLs approached target doctors and informed them of an interest in funding research opportunities and clinical trials at their practices and institutions. Doctors who were willing to speak favorable about Acthar could receive substantial funds in the form of research grants or other monies. In addition, these doctors were frequently remunerated for other less-defined services, including "consulting" and "advisory board" services. Mallinckrodt instructed its sales department to select doctors at the major teaching hospitals to become Acthar "experts' and KOLs who would in turn deliver the Acthar message to other physicians to row sales. This was done formally to other physicians at marketing events or informally to colleagues within a hospital or medical practice, or at a dinner or lunch roundtable.

468. Having recruited these physicians, Defendants' Acthar Marketing Enterprise created an explosion in the off-label use of Acthar by artificially creating the perception that physician specialists were clinically using Acthar and investigating with positive results their efficacy in off-label uses on their own initiative, and not as a result of the illegal marketing activities and inducements. Mallinckrodt developed a stable of physicians to create this perception. Mallinckrodt paid these physicians to induce them to write PA denial appeals, letters to the editor and other documents that favorably discussed the off-label use of Acthar. Mallinckrodt also paid these physicians (in addition to providing free travel to resorts, free lodging and free meals) to induce them to give talks at medical education seminars, advisory boards, consultants'' meetings, speakers bureaus and similar events where the primary focus of

the discussion was the off-label use of Acthar. The physicians who accepted these benefits and agreed to promote Acthar off-label to other doctors were physician participants in the Defendants'' Acthar Marketing Enterprise. The individual physician participants received tens of thousands of dollars, and in some cases hundreds of thousands, to promote the off-label uses of Acthar. Participation in the Enterprise through sham "authorships" and serving as presenting "faculty" at CME events and other honoraria also enhanced the physician participants' professional reputations.

469. The return on investment ("ROI") in Defendants' Marketing Enterprise was highly favorable.

470. Physician participants were absolutely critical to the success of Defendants' Acthar Marketing Enterprise. Indeed, the marketing pans drafted by Mallinckrodt required their participation. The participation of physicians allowed Mallinckrodt to disguise promotional events as educational events or consultants'' meetings. Moreover, as noted above, Mallinckrodt and UBC knew that peer-to-peer selling was far more persuasive than traditional drug rep detailing.[12] Primary care physicians are more likely to follow the advice of a Professor of Medicine at Johns Hopkins or another teaching hospital than that of a sales rep. By funneling the payments to physician participants through the vendor participants, the Acthar Marketing Enterprise could hide the speakers' financial ties with Defendants, and the Enterprise was able to mislead the physician-listeners into believing that the speakers were not biased and that the events were not promotional. As a result, the vast amounts of money the participating physicians

[12] When a sales representative "details" a physician, often during a all to the physicians' office during work hours, the representative delivers to the physician the pharmaceutical company's key selling messages for one or more pharmaceutical products. In some cases, the sales pitch is accompanied by handing out free samples of the product and/or approved materials delivered to the physician, such as sales aids, slides or branded merchandise such as pens and prescription pads. Here, Defendants were able to steer physicians through ASAP to UBC for PAP.

received from the Defendants, for speaking and other purposes, was largely hidden from the physicians who attended events at which the participating physicians spoke.

471. Physicians who participated in the Acthar Marketing Enterprise either as speakers or as authors, entered into mutually advantageous contractual relationships with Mallinckrodt. The more favorable a physician's statements were, the more he or she could expect to receive in the form of speaker fees, consulting fees, advisory board fees, and research grants. Physicians who refused to deliver the favorable off-label message that Mallinckrodt wanted were blackballed and would not receive additional payments.

472. The participating physicians knew that minimal scientific evidence supported the use of Acthar for the off-label uses and that the type of clinical evidence that existed was insufficient, under the accepted standards in the medical profession, to represent that Acthar worked for the unapproved indications.

473. All of the physician participants had personal relationships with employees of Defendants, whether the Mallinckrodt sales reps and MSLs, or the UBC RSs, and frequently Mallinckrodt recommended specific individual participants for event.

474. Plaintiff does not at this time know the identity of all of the physician participants, which likely number in the hundreds.

475. The Defendants' Acthar Marketing Enterprise sponsored hundreds of events across the country between 2007 and the present. Through Propublica, the Plaintiff is only able to identify physicians by payments, including travel, food, lodging and entertainment benefits they received for events held at resorts or out of town hotels.

476. In order to implement their respective plans to transform Acthar into the blockbuster drug it has become, despite a small on-label patient population, Acthar created a

separate Acthar Marketing Enterprise composed of each Defendant, and dozens of physician participants, some of whom are listed above and others whose identities will be revealed in discovery. These participants all acted together and under each Defendants' control in promoting Acthar's off-label to the healthcare industry, employing numerous tactics with an enormous degree of success.

477. Mallinckrodt hosted numerous seminars and events over the course of several years that were falsely represented to be neutral, educational forums. At these events, the roster of physician participants provided misleading and deceptive information to fellow physicians on the off-label uses of Acthar (i.e. peer-to-peer marketing). The physician participants were not independent, but received behind-the-scenes coaching and remuneration from Mallinckrodt and/or its vendors, and often used slide decks and PowerPoint presentations prepared by the marketing teams of Mallinckrodt Targeted audience members, many of whom were primary care physicians or specialists in MS, NS and RA, were not aware that the specialists (including prominent neurologist and nephrologists) speaking to them were in fact delivering, and being paid to deliver, the off-label marketing message of Mallinckrodt.

478. In addition, the sales force of Mallinckrodt promoted Acthar to physicians through "details" or sales calls to physicians' offices. On these sales calls, sales representatives-often using a sales aid and/or sales script developed by Mallinckrodt "detail" the physician on the off-label uses of Acthar. In addition, the sales representatives were instructed to deliver to physicians reprints of medical journal articles advocating the off-label use of Acthar, many of which were created by the KOLs paid by Mallinckrodt, and to notify physicians of and ask for their attendance at upcoming CME events and lectures sponsored by Mallinckrodt pursuant to

the Acthar Marketing Enterprise. All aspects of each Defendants' Acthar Marketing Enterprise were mutually reinforcing.

479. All components of each Defendants' Acthar Marketing Enterprise were fully integrated and operated under each Defendants' exclusive control, through the ASAP program.

DEFENDANTS' USE OF THE MAILS AND WIRES TO CREATE AND MANAGE THEIR FRAUDULENT SCHEME

480. Defendants used, and knowingly caused the use of, mail and interstate wire communications to create, execute, and manage their fraudulent schemes, as well as to further them. This scheme involved the national marketing and sale plan that comprised ASAP, and encompassed physicians and consumers across the country.

481. Defendants' use of, and causing the use of, the mails and wires in furtherance of their schemes to defraud involved thousands of communications and transmission through the Class period all over the country, including:

- Transmission through mail and wire marketing and advertising materials about the off-label uses of Acthar to and from physicians across the country, including and especially the Acthar Start Forms which were faxed to UBC;
- Communications and transmissions, including financial payments, from Defendants or vendors to participants in the Acthar Marketing Enterprise, including physicians, discussing and relating to the production and publication of articles and dissemination of materials misrepresenting the off-label uses and safety and efficacy of Acthar.
- Communications with Plaintiff and the Class Members and their beneficiaries, other health insurers, and patients, including payments for Acthar to be made based on misrepresentations concerning their safety, efficacy, effectiveness, and usefulness; and
- Communications, payments and monetary transfers using the wires concerning the receipt and distribution of the proceeds of Defendants' improper scheme.

482. In addition, Defendants' respective corporate headquarters have communicated, and knowingly cause communications, by United States mail, telephone and facsimile with or by

various local district managers, MSLs, RSs and pharmaceutical sales representatives, in furtherance of Defendants' scheme.

COUNT I
VIOLATION OF 18 U.S.C. § 1962(C)

483. Plaintiff hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further alleges as follows:

484. Defendants are each "persons" within the meaning of 18 U.SC. § 1961(3), who each conducted the affairs of the Acthar Marketing Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c). Plaintiff and the members of the Class are also persons.

485. The Acthar Marketing Enterprise is an association in fact enterprise affecting interstate commerce within the meaning of 18 U.S.C. § 1961(4) consisting of (i) Mallinckrodt, and its MSLs and sales representatives, (ii) UBC, and its RSs, and (iii) KOLs, both named and unnamed in this Complaint. At all relevant times, in violation of 18 U.S.C. § 1962(c), Mallinckrodt, UBC, the KOLs and other co-conspirators conducted the affairs of an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4), including their directors, employees, and agents who assisted in carrying out their alleged scheme.

486. The Acthar Marketing Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Acthar for off-label uses and doses and earning profits therefrom.

487. Mallinckrodt and UBC have conducted and participated in the affairs of the Acthar Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as

described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by Mallinckrodt and UBC throughout the Class Period number in the thousands, and Mallinckrodt and UBC committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period, a period which began in 2007 and continues through the present.

488. This enterprise was manifested by and through the ASAP program, but was made up of the three components of the alleged scheme: the Distribution Scheme, the Pricing Scheme and the Marketing Scheme. Accordingly, the enterprise concerned the marketing and sale of Acthar pursuant to the 2007 new strategy with each of these components described herein.

489. The Acthar Marketing Enterprise was begun in 2007, and is an ongoing and continuing business organization consisting of both corporations (*i*.e., Mallinckrodt and UBC) and individuals (*s* MSLs, RSs, KOLs), associated for the common purpose of distributing, pricing and marketing Acthar to Plaintiff and the Class at exorbitant AWP prices, and deriving substantial profits from these activities.

490. The Acthar Marketing Enterprise engages in and affects interstate commerce because it engages in the following activities across state boundaries: the distribution, pricing, marketing, sale, and/or purchase of Acthar, the transmission of WAC and AWP pricing information to the pricing compendia, ASAP program literature (including the Acthar Start Form at Exhibit "A" hereto), the operating of the ASAP program website, communications with providers, patients and TPPs by UBC as part of ASAP, and the transmission and/or the receipt of invoices and payments related to the prescription and use of Acthar. Through these activities the Acthar Enterprise markets, distributes and sells Acthar to thousands of individual patients, including those receiving prescription drug benefits from the Plaintiff and the Class.

491. The Acthar Marketing Enterprise has functioned as a continuing unit, as evidenced by the continuing coordination of activities between Mallinckrodt and UBC. There is a common communication network by which Mallinckrodt and UBC (and their agents and employees, including MSLs, RSs and KOLs) shared and continue to share information on a regular basis for all times relevant to this lawsuit, but beginning at least in 2007 and continuing through the present. Typically, this communication occurred by use of the wires and mails, in which Mallinckrodt, UBC and KOLs all agree to charge TPPs inflated AWP prices for Acthar to the patients of TPPs, like Local 420, and other Class members. These entities functioned as a continuing unit for the purposes of implementing the scheme to inflate the prices of Acthar by and through ASAP. When issues arose during the scheme, each agreed to take actions to hide the scheme and to continue its existence.

492. Defendants have exerted control over the Acthar Enterprise, have associations with the Enterprise, and have directly or indirectly conducted or participated in the conduct of the affairs of the ASAP Enterprise in the following ways:

a. Defendants have directly controlled the AWP price at which Plaintiff and the Class purchase Acthar;

b. Defendants have directly controlled the AWP price at which Plaintiff and the Class reimburse for Acthar;

c. Defendants have directly controlled the ASAP program materials and website which enroll patients in an exclusive distribution network for the administration of Acthar, allowing Mallinckrodt and UBC to conduct their unconscionable and unfair pricing of Acthar;

d. Defendants have directly controlled the exclusive distribution network for Acthar through the ASAP Enterprise;

e. Defendants have relied on their employees to promote the ASAP program through the marketing alleged herein, through the mail and the wires;

f. Defendants placed their own employees and agents in positions of authority and control over the Acthar Marketing Enterprise;

g. Defendants controlled the content of the messages being delivered by the Acthar Marketing Enterprise at each seminar, event, and presentation, in the publications being used and presented, in the direct communications with providers, patients and payors, all of which included misinformation and false and misleading statements about the safety, efficacy, effectiveness, usefulness, and value of Acthar for off-label uses;

h. Defendants have participated in the affairs of the ASAP Enterprise by using a fraudulent scheme to market and sell Acthar at inflated prices;

i. Mallinckrodt has selected and approved physicians to serve as KOLs, who in turn work with UBC under the ASAP to deliver off-label prescriptions of Acthar for payment by TPPs; and

j. Defendants worked to ensure that the Acthar prescribed by KOLs and other providers were paid for by TPPs at the inflated AWPs charged by them.

493. Defendants have conducted and participated in the affairs of the ASAP Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1345, relating to wire fraud. Defendants' pattern of racketeering activity likely involved hundreds, if not thousands, of separate instances of the use of the United States mail, private shipping services, facsimiles, or interstate wires, including the internet, in furtherance of its fraudulent and unlawful scheme. Each of these fraudulent mailing and interstate wire transmissions separately constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5) in which the Defendants intended to defraud Plaintiff and members of the Class.

494. As described in greater detail herein, Defendants' fraudulent scheme consisted of confining patients to an exclusive distribution network, such that they could drastically inflate the prices charged for Acthar. By conducting this program through the mail and wires,

Defendants engaged in a repeated, fraudulent, and unlawful course of conduct constituting a pattern of racketeering.

495. As detailed above, the Acthar Marketing Enterprise consisted of: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Acthar was safe and effective so the Plaintiff and the Class Members paid for this drug at inflated prices to treat conditions and/or symptoms for which it was not scientifically proven to be safe, effective, useful and valuable; (b) presenting seminars, events, in-person meetings and telephonic communications misrepresenting the off-label uses of Acthar for which Defendants knew Acthar was not proven to be scientifically safe, effective, useful or valuable to physicians and other healthcare providers; (c) disseminating materials created pursuant to the Acthar Marketing Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Acthar was safe, effective, useful and valuable; and (d) actively concealing, and causing others to conceal, information about the safety, efficacy, usefulness and value of Acthar to treat conditions for which it had not been approved by the FDA.

496. These racketeering activities amounted to a continuing course of conduct, with similar pattern and purpose, intended to harm Plaintiff and the Class to pay excessive amounts for Acthar. Each instance of racketeering activity perpetuated by the Defendants was related, and had a similar intended purpose, involved similar participants and methods of execution, and have the same results affecting the same class of victims, including Plaintiff and the Class. Defendants had engaged in this pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Acthar Marketing Enterprise.

497. Defendants' pattern of racketeering activities alleged herein are separate and distinct from each other.

498. Defendants' pattern of racketeering activities had directly and proximately caused Plaintiff and members of the Class to be injured in their property insofar as Plaintiff and members of the Class have overpaid thousands of dollars in inflated reimbursements and other payments for Acthar. Plaintiff's and the Class Members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening forces; their injuries were a foreseeable and natural consequence of the Defendants' scheme; there is no difficulty posed by having to apportion damages among Class Members with potentially different standing or levels of injury because there are no other injured parties besides Plaintiff and the TPP Class Members in this case, who are the parties directly injured by the Defendants' RICO violations. No one other than Plaintiff and the Class could vindicate the rights and claims of Plaintiff and the Class.

499. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the costs of this suit, including reasonable attorney's fees.

COUNT II
CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c)
(18 U.S.C. § 1962(d))

500. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein and further allege as follows.

501. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section." 18 USC § 1962(d).

502. Defendants violated section 1962(d) by conspiring to associate with a racketeering enterprise, in violation of 18 U.S.C. § 1962(c). Mallinckrodt knowingly joined

UBC and others in a conspiracy to inflate the prices of Acthar and marketing the off-label uses and doses of Acthar in violation of § 1962(c).

503. The object of this conspiracy is to and has been to conduct or participate in, directly or indirectly, the conduct of the affairs of the Acthar Marketing Enterprise described herein, through a pattern of racketeering activity that directly cause injury to the business or property of Plaintiff and the Class within the meaning of 18 U.S.C. § 1964(c). The corporate defendants conspired with, inter alia, the sales representatives, MSLs, RSs, KOLs and others to promote Acthar and suppress information about the harms know to result from Acthar use.

504. Defendants and their co-conspirators have engaged in numerous overt and predicate fraudulent racketeering activities in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class of money.

505. That Mallinckrodt knew and adopted the criminal purpose of the Enterprise is evident from its own documents and public statements of its officers. Mallinckrodt communications reflect an express illegal agreement between Mallinckrodt and UBC to form and operate the ASAP in furtherance of the Acthar Marketing Enterprise. Mallinckrodt's officers stated that it was this agreement in 2007 that was the hallmark of a new strategy to increase revenues and profits.

506. The nature of the above-described AbbVie Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracies gives rise to an inference that they not only agreed to the objective of an 18 U.S.C.§ 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity. In other words, the

Defendants adopted the goal of furthering or facilitating the conspiracy, and were aware of the essential nature and scope of the Acthar Marketing Enterprise and intended to participate in it.

507. Additionally, Defendants' conduct in sending e-mails, faxes and other communications to each other to direct the distribution and sale of Acthar through ASAP is consistent with the existence of an agreement to carry out the scheme to inflate prices and maximize profits.

508. Defendants actively furthered the goals of the Acthar Marketing Enterprise to defraud end payors, like Plaintiff. They changed the distribution scheme for Acthar with the intention that the changes would allow the Pricing Scheme to be effectuated; engaged in frequent discussions with between each other about the plan to raise Acthar prices and to promote the sale of Acthar at these new high prices for unapproved uses and doses in the marketplace; and communicated with KOLs and other providers about the same.

509. The Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts: a) multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342; b) multiple instances of mail fraud violation of 18 U.S.C §§ 1341 and 1346; c) multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and d) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

510. The Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue.

511. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have paid millions of dollars in

overpayments for Acthar that they would not have paid had the Defendants not conspired to violate 18 U.S.C. § 1962(c).

512. Injuries suffered by Plaintiff and members of the Class were directly and proximately caused by the Defendants' racketeering activity as described above. As also set forth above, these injuries would not have occurred but for the Defendants' RICO predicate act violations, and they involved concrete financial losses to the Plaintiff and the Class Members.

513. Patients, physicians, and TPPs, including Plaintiff and the Class, directly relied on the racketeering activities of the Defendants' and the Acthar Marketing Enterprise. Plaintiff and the Class Members, both directly and indirectly, relied on the representations as to the necessity, approval and safety of Acthar as promoted by the Defendants. Because the Defendants controlled all knowledge upon which the claims of Acthar's necessity, approval and safety were based, all Class Members, as well as other members of the medical and consuming public were obligated to rely on the Defendants' representations about Acthar. Further, the Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Acthar.

514. As co-conspirators, Mallinckrodt and UBC are jointly and severally liable for all damage that occurred as a result of both their actions in furtherance of the conspiracy to raise prices of Acthar and market the sale of Acthar at inflated prices for unapproved uses and doses. Mallinckrodt is liable for all damages arising from UBC's conduct in furtherance of the scheme, as it UBC liable for all damages from Mallinckrodt's conduct in furtherance of the scheme.

515. By virtue of these violations of 18 U.S.C. § 1962(d), the Defendants are liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

516. By reason of the foregoing, and as a direct and proximate result of the Defendants' fraudulent misrepresentations, Plaintiff and the Class Members have suffered damages. Plaintiff and the Class Members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

517. By reason of the foregoing, Plaintiff and the Class Members have been damaged as against the Defendants in a sum that exceeds the jurisdiction of all lower courts.

COUNT III
PENNSYLVANIA UNFAIR TRADE PRACTICES AND
CONSUMER PROTECTION LAW

518. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

519. Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. §§201, et seq. ("UTPCPL") makes unlawful any "unfair methods of competition" and "unfair or deceptive acts or practices", including the following, among others:

> (ii) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services;
>
> (v) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have;
>
> (vii) Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another;
>
> (viii) Disparaging the goods, services or business of another by false or misleading representations of fact;
>
> (xi) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions; and
>
> (xxi) Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

520. The unfair methods of competition, and unfair or deceptive acts or practices, in the conduct of any trade or commerce as defined above are declared unlawful under the UTPCPL.

521. Defendants engaged in the following unfair and deceptive acts or practices, which violate the aforesaid provisions of the UTPCPL:

a. By entering into the exclusive distribution arrangement described herein in 2007, and not disclosing the same to Local 420, Mallinckrodt and UBC engaged in deceptive acts and made misrepresentations to Plaintiff and its beneficiary that impeded Plaintiff's efforts to contain costs for specialty drugs like Acthar. By then sending (or causing to be sent) bills for Acthar which charged the artificially inflated prices, and by communicating directly with patients about the misleading messages described above, Mallinckrodt injured Plaintiff and the Class. This caused at least a likelihood of confusion or of misunderstanding as to the source, sponsorship, approval and/or certification of Acthar sold by Mallinckrodt, misrepresented the same, and/or constituted fraudulent or deceptive conduct which created a likelihood of confusion or a misunderstanding by Plaintiff.

b. Defendants conspired and agreed to adopt the above-described ASAP program and the Acthar Start Form in 2007, and to maintain and use the ASAP and Acthar Start Form through 2018 (when Plaintiff paid for Acthar), in order to mislead and deceive Local 420 and its beneficiary about the Mallinckrodt "hub" of patient care at UBC as it concerns the new conditions for which Acthar is not indicated, and to bypass Plaintiff's efforts to contain and reduce costs for specialty drugs, especially for new indications.

c. Starting in July 2007, Mallinckrodt issued a misleading and deceptive announcement about its new distribution strategy, but the announcement failed to disclose that all aspects of Acthar distribution, pricing and product sales were now being coordinated through UBC as part of a "hub" of services for which Mallinckrodt contracted.

d. Mallinckrodt and UBC misled and deceived Local 420 in the decision to raise the prices of Acthar, and the lack of value of Acthar for the prices being charged, in order to intentionally and

deceptively charge false, misleading and excessive prices for Acthar, during the period between 2007 (when Mallinckrodt adopted its "new strategy" they entered into their exclusive distribution and hub arrangement), through 2018 (when Local 420 began to pay for Acthar). Mallinckrodt then falsely claimed to offer discounts off the inflated prices of Acthar, thereby misleading Plaintiff as to the reasons for, existence of, or amounts of the Acthar price reductions, in violation of sub-section (xi).

e. Defendants acts or practices, including the failures to act and to speak the truth in the face of false, misleading and deceptive statements about Acthar's pricing, distribution and value, constitute "other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding, in violation of sub-section (xxi).

522. The UTPCPL authorizes any person, including natural persons, corporations, trusts, partnerships, incorporated and unincorporated associations, and any other legal entities to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and ameliorate the anticompetitive conducted described herein.

523. Local 420 is a person pursuant to the UTPCPL. Local 420 has been injured as a result of the Defendants' conduct in violation of Pennsylvania law, by virtue of having paid for Acthar in Pennsylvania, and hereby seeks damages. Plaintiff has purchased or reimbursed the costs of multiple administrations of Acthar distributed by Defendants to Local 420 's beneficiary for her personal, family or household use and purpose. Because Local 420's beneficiary paid only a minimal co-pay ($70), Local 420 paid the bulk of the inflated prices of Acthar to Mallinckrodt.

524. The acts and practices described herein demonstrate that Mallinckrodt acted unlawfully within the meaning of the UTPCPL such that Local 420 may be awarded up to three times its actual damages sustained, and such additional relief as deemed necessary or proper. These damages consist of, inter alia, the difference between the true price of Acthar, before

Mallinckrodt began in 2007 to artificially inflate the "average wholesale price" of Acthar, and the inflated prices of Acthar charged to Plaintiff in 2018. The damages of the Class may be calculated in the same manner.

525. Local 420 seeks relief against Mallinckrodt for tits unfair and deceptive conduct which allowed it to raise and fix the prices of Acthar at supra-competitive levels.

526. Local 420 was injured as a direct result of Mallinckrodt's conduct in violation of the UTPCPL sections above, and hereby seeks damages.

WHEREFORE, Steamfitters Local Union No. 420 demands that judgment be entered in its favor and against Defendants in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT IV
DEFENDANTS' VIOLATIONS OF OTHER STATE CONSUMER PROTECTION LAWS

527. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows:

528. Mallinckrodt violated the consumer protection laws of all other states by engaging in unfair methods of competition and unfair deceptive acts and practices as described herein. Plaintiff brings claims under the laws of these states on behalf of the consumer purchasers of Acthar in such states. Excluded from this case are the states of Iowa which do not allow consumers to sue. Plaintiff does not seek class certification of consumer fraud claims under the laws of Alabama, Georgia, Mississippi, and South Carolina, as those state laws do not permit class actions. However, the individual claims of consumers in those states should be permitted to be advanced in this lawsuit to benefit from those this Court's rulings on Mallinckrodt's conduct, especially as to the declaratory and injunctive relief sought by the Plaintiff.

Alabama's Deceptive Trade Practices Act ("Alabama DTPA")
Ala. Code §§ 8-19-1, *et seq.*

529. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alabama's Deceptive Trade Practices Act, Ala. Code § 8-19-1, et seq.

530. Alabama Code § 8-19-5(27) declares that "[e]ngaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce" is unlawful.

531. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Alabama DTPA.

532. The DTPA authorizes any person, including "a natural person, corporation, … " to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

533. Mallinckrodt marketed and sold Acthar in Alabama pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

534. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Alabama are persons under the DTPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the DTPA, and each hereby seeks damages, through their representative Local 420.

Alaska's Unfair Trade Practices and Consumer Protection Act ("UTPCPA") Alaska Stat. §§ 45.50.471, *et seq*.

535. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska's Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471, et seq.

536. Alaska Statute 45.50.471(a) declares that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce" are unlawful. Alaska Statute 45.50.471(b)(12) provides that the terms "unfair methods of competition" and "unfair or deceptive acts or practices" include using or employing deception, fraud, false pretense, false promise, misrepresentation, or knowingly concealing, suppressing, or omitting a material fact with intent that others rely upon the concealment, suppression or omission in connection with the sale or advertisement of goods or services, whether or not a person has in fact been misled, deceived or damaged.

537. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Alaska UTPCPA.

538. The UTPCPA authorizes any person, including "a natural person, corporation, … " to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

539. Mallinckrodt marketed and sold Acthar in Alaska pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

540. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Alaska are persons under the UTPCPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the UTPCPA, and each hereby seeks damages, through their representative Local 420.

Arizona Consumer Fraud Act ("Arizona CFA")
Ariz. Rev. Stat. § 44-1522, *et seq*.

541. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Arizona CFA, Ariz. Rev. Stat. § 44-1522, et seq..

542. The Arizona CFA is a broadly drafted remedial provision designed to eliminate unlawful practices in merchant-consumer transactions.

543. By the Arizona CFA, an unlawful practice is defined as follows: "[t]he act, use, or employment by any person of any deception, deceptive act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived, or damaged thereby . . ." § 44-1522(A).

544. The term "deceptive" has been interpreted to include representations that have a "tendency and capacity" to convey misleading impressions to consumers even though interpretations that would not be misleading also are possible.

545. Technical correctness of the representations is irrelevant if the capacity to mislead is found. Additionally, a deceptive representation or practice may be found where earlier misrepresentations are corrected before the consumer agrees to a contract.

546. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Arizona CFA.

547. The CFA authorizes any person, including "a natural person, corporation, … " to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

548. Mallinckrodt marketed and sold Acthar in Arizona pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

549. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Arizona are persons under the CFA. Each has been injured as a direct

and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the CFA, and each hereby seeks damages, through their representative Local 420.

Arkansas Deceptive Trade Practices Act ("ADTPA")
Ark. Code § 4-88-101, *et seq*.

550. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, et seq.

551. Among other things, Ark. Code Ann. § 4-88-107 prohibits "[k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification of goods or services. . . ." and prohibits "[a]dvertising the goods or services with the intent not to sell them as advertised. . . ." Ark. Code Ann. § 4-88-107 (a)(1) & (3).

552. Under Ark. Code Ann. § 4-88-113 (f), a private cause of action is afforded to any person who suffers actual damage or injury.

553. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the ADTPA.

554. The ADTPA authorizes any person, including "a natural person, corporation, … " to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

555. Mallinckrodt marketed and sold Acthar in Arkansas pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

556. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Arkansas are persons under the ADTPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the ADTPA, and each hereby seeks damages, through their representative Local 420.

California Business and Professions Code ("Section 17200"),
Cal. Bus. & Prof. Code § 17200, et seq

557. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, et seq.

558. Section 17200 is violated if a business practice is unlawful or unfair or deceptive. "[A] practice is prohibited as 'unfair' or 'deceptive' even if not 'unlawful' and vice versa."

559. To show that a business practice is deceptive, the plaintiff must show that members of the public are likely to be deceived.

560. The deceptive business practices prong of Section 17200 does not require establishing that anyone was actually deceived, relied on the fraudulent practice or sustained any damage.

561. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under Section 17200.

562. Section 17200 authorizes any person, including "a natural person, corporation, … " to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

563. Questcor was originally based in California and marketed and sold Acthar throughout California pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein. Mallinckrodt, now based in New Jersey, has continued such conduct.

564. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in California are persons under Section 17200. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of Section 17200, and each hereby seeks damages, through their representative Local 420.

Colorado Consumer Protection Act (CCPA),
Colo. Rev. Stat. § 6-1-105, et seq.

565. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, et seq.

566. To establish a claim under the Colorado Consumer Protection Act (CCPA), a private citizen must prove five elements: (1) the defendant engaged in an unfair or deceptive trade practice; (2) the deceptive trade practice occurred in the course of the defendant's business; (3) the deceptive trade practice significantly impacted the public as actual or potential customers of the defendant's business; (4) the plaintiff suffered an injury to a legally protected interest; and (5) the deceptive trade practice caused the plaintiff's injury.

567. The unconscionable, unfair and deceptive acts and practices described herein are thus unlawful under CCPA. Mallinckrodt engaged in the unfair and deceptive trade practices described herein, which deceptive trade practices occurred in the course of the defendant's business. The deceptive trade practice significantly impacted the public as actual or potential customers of the defendant's business. Members of the Class who purchased Acthar in Colorado suffered an injury to a legally protected interest by their payment of money for a drug that was unapproved, unsafe, ineffective and cost more than other equally or more effective medicines. The deceptive trade practice thus caused the plaintiff's injury.

568. Mallinckrodt marketed and sold Acthar in Colorado pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

569. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Colorado are persons under the CCPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the CCPA, and each hereby seeks damages, through their representative Local 420.

Connecticut Unfair Trade Practices Act ("CUTPA"),
Conn. Gen. Stat. § 42-110b, et seq.

570. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, et seq.

571. The CUPTA expressly admonishes that "[n]o person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110b(a). The same section also provides that "[i]t is the intent of the legislature that in construing subsection (a) if this section [that] the courts of this state shall be guided by interpretations given by the [FTC] and the federal courts to Section 5(a)(1) of the Federal Trade Commission Act.

572. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the CUTPA.

573. The CUTPA authorizes any person, including "a natural person, corporation, limited liability company, trust, partnership, incorporated or unincorporated association, and any other legal entity" to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

574. Members of the Class who purchased Acthar at inflated prices are persons pursuant to the CUTPA and each has been injured as a result of the Defendants' unconscionable, unfair, and deceptive conduct in violation of the CUTPA, and hereby seeks damages. One such person is Sheet Metals Workers Local 40 of Hartford Connecticut ("SMW Local 40"), represented by the same undersigned Plaintiff counsel. SMW Local 40 has sued separately in Connecticut state court.

575. The facts and circumstances described herein demonstrate that Mallinckrodt acted unlawfully within the meaning of the CUTPA such that members of the Class may be awarded

actual damages sustained as well as punitive damages, and such additional, equitable relief as deemed necessary or proper.

576. Plaintiff and the Class seek relief against Mallinckrodt for its unconscionable, unfair, and deceptive commercial practices with regard to their scheme to sell Acthar to patients through KOLs at inflated prices by an unfair and deceptive scheme involving kickbacks and other inducements.

577. Mallinckrodt created restrictions on trade and commerce in Connecticut through the creation of the exclusive arrangement for the distribution and sale Acthar.

578. Mallinckrodt then agreed to raise the prices of Acthar to inflated levels, and charged such prices in Connecticut to TPPs like SMW Local 40. As described herein, Mallinckrodt charged the supracompetitive prices of Acthar through the ASAP Program.

579. This unconscionable, unfair, and deceptive conduct caused members of the Class in Connecticut, like SMW Local 40, to pay prices for Acthar significantly greater than in an otherwise competitive market. Therefore, SMW Local 40 and members of the Class in Connecticut are entitled to relief under the CUTPA.

580. Plaintiff and the Class were injured as a direct and proximate result of the Mallinckrodt's conduct in violation of Connecticut law and hereby seek declaratory and injunctive relief and damages.

Consumer Fraud Act ("Delaware CFA"),
Del. Code Ann. tit. 6, § 2513

581. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, et seq.

582. The unconscionable, unfair and deceptive acts and practices described herein are thus unlawful under Delaware CFA.

583. Mallinckrodt marketed and sold Acthar in Delaware pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

584. Specifically, the beneficiary of Local 420 resides in Delaware. Although she treated with a rheumatologist in Pennsylvania, she was obligated to pay a copay for Acthar.

585. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Delaware are persons under the CFA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the CFA, and each hereby seeks damages, through their representative Local 420 and its Delaware-based beneficiary.

District of Columbia Consumer Protection Procedures ("DCCPP")
D.C. Code § 28-3904, *et seq.*

586. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3904, et seq.

587. D.C. Code § 28-3904 states "[i]t shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice, whether or not any consumer is in fact misled, deceived, or damaged thereby."

588. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the DCCPP.

589. The DCCPP authorizes any person, including "a natural person, corporation, … " to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

590. Mallinckrodt marketed and sold Acthar in Arkansas pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

591. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in the District of Columbia are persons under the DCCPP. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the DCCPP, and each hereby seeks damages, through their representative Local 420.

Florida Deceptive & Unfair Trade Practices Act ("FDUTPA")
Florida Stat. §§ 501.201, et seq.

592. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.

593. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Florida Stat. §§ 501.202(2).

594. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

595. Under Florida law, indirect purchasers of prescription drugs, like Plaintiff and the Class, have standing to maintain an action under the FDUTPA based on the facts alleged in this Complaint. Undersigned counsel for Plaintiff represents purchasers of Acthar located within Florida, who have decided to bring suit on their own behalf in Florida state court under FDUTPA.

596. Mallinckrodt's conduct constitutes an unfair method of competition and unfair and deceptive acts or practices because Mallinckrodt's conduct caused Florida-based members of the Class to pay artificially inflated prices for Acthar.

597. Mallinckrodt sold Acthar in Florida through the ASAP Program, based out of Orlando Florida, through Express Scripts subsidiary companies located in Florida, including United BioSource and Curascript. Such sales in Florida this took place under the circumstances and conditions described in this Complaint, and Mallinckrodt's conduct had a direct and substantial impact on trade and commerce in Florida. Accordingly, such conduct falls within the prohibitions in Florida Stat. §§ 501.202(2).

598. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the FDUPTA.

599. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Florida have standing to sue under the FDUPTA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the FDUPTA, and each hereby seeks damages, through their representative Local 420.

Georgia Fair Business Practices Act ("FBPA")
Ga. Code Ann. §§ 10-1-390, *et seq.*

600. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Code § 10-1-393, et seq.

601. Ga. Code § 10-1-393(a) "[u]nfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce are declared unlawful."

602. Mallinckrodt's conduct constitutes unfair or deceptive acts or practices in the trade or commerce of Georgia. Specifically, as described in part above, Tennessee-based Dr. Tumlin travelled to Georgia on multiple occasions as a Mallinckrodt paid KOL to promote

Mallinckrodt's misleading and deceptive message about Acthar's MOA and FDA approval, especially for NS. In fact, Dr. Tumlin travelled to suburban Atlanta for one such session.

603. As a result, doctors in Georgia became Mallinckrodt KOLs. One such doctor, Dr. Wilson, is described by former Mallinckrodt employee Barry Franks as having been part of the Mallinckrodt scheme to promote Acthar. Dr. Wilson treated a beneficiary of one of the Georgia-based clients of undersigned Plaintiff counsel. To date, such client has incurred over $2 million in payments for Acthar, and continues to do so. The patient being treated with Acthar by Dr. Wilson is being treated for what is believed to be an off-label indication of NS. Specifically, the patient has been prescribed Acthar as a maintenance medication for the treatment of NS for multiple years. For his work on behalf of Mallinckrodt, Dr. Wilson has been paid thousands of dollars. Mallinckrodt has paid for Dr. Wilson to travel to multiple vacation locations as its "consultant" and has paid all the costs of such trips, as well as thousands of dollars of "consultant" fees and "honoraria".

604. Mallinckrodt's conduct caused Georgia-based members of the Class to pay artificially inflated prices for Acthar.

605. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Georgia FBPA.

606. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Georgia have standing to sue under the FBPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the FBPA, and each hereby seeks damages, through their representative Local 420.

Hawaii Unfair and Deceptive Trade Practice Act ("UDAP"),
Haw. Rev. Stat. § 480, *et seq*.

607. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, et seq.

608. Haw. Rev. Stat. § 480-2(a) states that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful".

609. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Hawaii UDAP.

610. Mallinckrodt marketed and sold Acthar in Hawaii pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein

611. Only consumers, the attorney general, or the director of the office of consumer protection may bring a UDAP claim. HRS § 480-2(d). Consumers include those who "(1) purchased, attempted to purchase, or been solicited to purchase goods or services from the defendant, or (2) committed money, property, or services in a personal investment."

612. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at the inflated prices set by Mallinckrodt and charged in Hawaii are persons under the Hawaii UDAP. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the Hawaii UDAP, and each hereby seeks damages, through their representative Local 420.

613. The Hawaii UDAP also provides that "[a]ny consumer who is injured by any unfair or deceptive act or practice forbidden or declared unlawful by section 480-2: (1) May sue for damages sustained by the consumer, and, if the judgment is for the plaintiff, the plaintiff shall be awarded a sum not less than $ 1,000 or threefold damages by the plaintiff sustained, whichever sum is the greater, and reasonable attorneys fees together with the costs of suit; and

(2) May bring proceedings to enjoin the unlawful practices, and if the decree is for the plaintiff, the plaintiff shall be awarded reasonable attorneys fees together with the cost of suit."

614. Thus, it is not necessary that any Hawaii consumer suffered actual injury from their receipt and/or purchase of Acthar. As the Hawaii Supreme Court has held, "the plain language of the statute reflects that the legislature intended not only to protect persons who actually purchased goods or services as a result of unfair or deceptive acts and practices, but also those who attempted or were solicited to do so. … The $1,000.00 assured minimum recovery manifests a legislative intent to do more than simply prevent unjust enrichment at the expense of consumers who purchased relatively inexpensive goods." *Zanakis-Pico v. Cutter Dodge, Inc*., 98 Haw. 309, 316, 317 (2002).

Idaho Consumer Protection Act (ICPA),
Idaho Code § 48-601, *et seq*

615. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, et seq.

616. Idaho Code § 48-603 provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared to be unlawful…"

617. The ICPA was enacted to protect consumers from "deceptive acts and practices in the conduct of trade or commerce." I.C. § 48-601. "[T]he ICPA defines what constitutes an unfair method of competition." *State ex rel. Wasden v. Daicel Chem. Indus., Ltd.*, 141 Idaho 102, 107, 106 P.3d 428, 433 (2005).

618. Under I.C. §48-603, "deceptive acts or practices in the conduct of any trade or commerce are unlawful where a person knows, or in the exercise of due care should know, that he has in the past, or is:

> (2) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
> (3) Causing likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another;
> (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have …;
> (11) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;
> (17) Engaging in any act or practice which is otherwise misleading, false, or deceptive to the consumer;
> (18) Engaging in any unconscionable method, act or practice in the conduct of trade or commerce, as provided in section 48-603C, Idaho Code . . .

I.C. § 48-603 (2)-(3), (5), (11), (17)-(18)(statute excerpted for relevant portions only).

619. Section 48-603C defines "unconscionable methods, acts or practices" as follows:

i. Any unconscionable method, act or practice in the conduct of any trade or commerce violates the provisions of this chapter whether it occurs before, during, or after the conduct of the trade or commerce.

ii. In determining whether a method, act or practice is unconscionable, the following circumstances shall be taken into consideration by the court:

> (a) Whether the alleged violator knowingly or with reason to know, took advantage of a consumer reasonably unable to protect his interest because of physical infirmity, ignorance, illiteracy, inability to understand the language of the agreement or similar factor;
> (b) Whether, at the time the consumer transaction was entered into, the alleged violator knew or had reason to know that the price grossly exceeded the price at which similar goods or services were readily available in similar transactions by similar persons, although price alone is insufficient to prove an unconscionable method, act or practice;
> (c) Whether the alleged violator knowingly or with reason to know, induced the consumer to enter into a transaction that was excessively one-sided in favor of the alleged violator;
> (d) Whether the sales conduct or pattern of sales conduct would outrage or offend the public conscience, as determined by the court.

620. Beyond these legislative definitions of unfair competition, I.C. § 48-604 instructs that "[i]t is the intent of the legislature that in construing [the ICPA] due consideration and great weight shall be given to the interpretation of the federal trade commission and the federal courts

relating to section 5(a)(1) of the federal trade commission act (15 U.S.C. 45(a)(1)), as from time to time amended."

621. Section 5(a)(1) of the FTCA provides that "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful." 15 U.S.C. § 45(a)(1). "Federal case law as it has developed under this provision of the [FTCA], although not binding is persuasive in application of the [ICPA]." *State ex rel. Kidwell v. Master Distribs., Inc., 101 Idaho 447, 453, 615 P.2d 116, 122 (1980).*

622. The acts and omissions of Mallinckrodt set forth herein violate the ICPA in multiple respects.

623. First, like the similar subsections of the Pennsylvania UTPCPL, Mallinckrodt's actions violate the above-cited enumerated subsections of I.C. § 48-603 (2)-(3), (5), (11), (17)-(18).

624. Second, like the similar provisions of New Jersey law below, Mallinckrodt's actions constitute unconscionable business practices because (1) Mallinckrodt "knowingly or with reason to know, took advantage of a consumer reasonably unable to protect his interest because of physical infirmity due to the diseases for which they were prescribed Acthar; (2) "at the time the consumer transaction was entered into, [Mallinckrodt] knew or had reason to know that the price [for Acthar] grossly exceeded the price at which similar goods or services were readily available in similar transactions by similar persons," given the substantially cheaper costs of prednisone and other steroids; (3) Mallinckrodt "knowingly or with reason to know, induced the consumer to enter into a transaction that was excessively one-sided in favor of the alleged violator", in light of the role of the Mallinckrodt HUB, the MSLs, the KOLs, the PAPs and other aspects of Mallinckrodt's scheme to ensure sales of Acthar at high prices; and (4) the fact that

"the sales conduct or pattern of sales conduct would outrage or offend the public conscience", as determined by the court based on, among other things, the Acthar price change from $40.00 to over $40,000 for a drug with limited uses and benefits.

625. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Idaho are consumers under the ICPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the ICPA, and each hereby seeks damages, through their representative Local 420.

Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1, *et seq*

626. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, et seq.

627. 815 ILCS § 505/2 states that "[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5 (a) of the Federal Trade Commission Act."

628. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Illinois Act.

629. The Illinois Act authorizes any person, including "a natural person, corporation, … " to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

630. Mallinckrodt marketed and sold Illinois in Alabama pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

631. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Illinois are persons under the Illinois Act. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the Illinois Act, and each hereby seeks damages, through their representative Local 420.

Kansas Unfair Trade and Consumer Protection,
Kan. Stat. § 50-623

632. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, et seq.

633. Kan. Stat. § 50-626(a) states that [n]o supplier shall engage in any deceptive act or practice in connection with a consumer transaction; Kan. Stat. § 50-626(b): "[d]eceptive acts and practices include, but are not limited to, the following, each of which is hereby declared to be a violation of this act, whether or not any consumer has in fact been misled": (3) "the will failure to state a material fact, or the willful concealment, suppression or omission of a material fact"; (7) "making false or misleading representations, knowingly or with reason to know, of fact concerning the reason for, existence of or amounts of price reductions, or the price in comparison to prices of competitors or one's own price at a past or future time"; (8) "falsely stating, knowingly or with reason to know, that a consumer transaction involves consumer rights, remedies or obligations".

634. Under Kan. Stat. § 50-627(a), "[u]nconscionable acts and practices, [n]o supplier shall engage in any unconscionable act or practice in connection with a consumer transaction. An unconscionable act or practice violates this act whether it occurs before, during or after the transaction."

635. Kan. Stat. § 50-627(b)(1) states that "[t]he supplier took advantage of the inability of the consumer reasonably to protect the consumer's interests because of the consumer's physical infirmity, ignorance, illiteracy, inability to understand the language of an agreement or similar factor".

636. Kan. Stat. § 50-627(b)(2) states that "when the consumer transaction was entered into, the price grossly exceeded the price at which similar property or services were readily obtainable in similar transactions by similar consumers."

637. Kan. Stat. § 50-627(b)(5) "the transaction the supplier induced the consumer to enter into was excessively one sided in favor of the supplier".

638. Kan. Stat. § 50-627(b)(6) "the supplier made a misleading statement of opinion on which the consumer was likely to rely to the consumer's detriment."

639. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Kansas law.

640. Kansas authorizes any person, including "a natural person, corporation, … " to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

641. Mallinckrodt marketed and sold Acthar in Kansas pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

642. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Kansas are persons under the Kansas Act. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the Kansas Act, and each hereby seeks damages, through their representative Local 420.

Kentucky Revised Statutes,
Consumer Protection - Ky. Rev. Stat. § 367.110, *et seq*.

643. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, et seq.

644. Under Ky. Rev. Stat. § 367.170(1) "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful; (2) [f]or the purposes of this section, unfair shall be construed to mean unconscionable."

645. Ky. Rev. Stat. § 367.175(2) "[i]t shall be unlawful for any person or person to monopolize, or attempt to monopolize or combine or conspire with any other person or persons to monopolize any part of the trade or commerce in this Commonwealth."

Louisiana Revised Statues – Unfair Trade Practices and Consumer Protection Law
La. Rev. Stat. § 51:1401, *et seq*

646. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, et seq.

647. Under La. Rev. Stat. § 51:1405(A) "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

Maine Unfair Trade Practices Act,
5 Me. Rev. Stat. § 207, *et seq*

648. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, et seq.

649. 5 Me. Rev. Stat. § 207 "Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful." 5 Me. Rev. Stat. § 207(1) "[T]he courts will be guided by the interpretations given by the Federal Trade Commission and the Federal Courts to Section 45(a)(1) of the Federal Trade Commission Act (15 United States Code 45(a)(1))…".

Maryland Consumer Protection Act,
Md. Com. Law Code § 13-101, *et seq*

650. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, et seq.

651. Maryland Unfair or deceptive trade practices include "[f]alse, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers". Md. Com. Law Code § 13-301(1). Any representation "fail[ing] to state a material fact if the failure deceives or tends to deceive" is unlawful. Md. Com. Law Code § 13-301(3).

652. "A price in comparison to price of a competitor or to one's own price at a past or future time". Md. Com. Law Code § 13-301(6)(ii).

653. Md. Com. Law Code § 13-301(9) "Deception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that consumer rely on the same in connection with (i) [t]he promotion or sale of ay consumer goods, consumer realty or consumer service".

Massachusetts Consumer Protection Act ("MCPA")
Mass. Gen. L. Ch. 93A, et seq.

654. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et. seq. ("MCPA").

655. The MCPA regulates trade and commerce "directly or indirectly affecting the people of this commonwealth." Mass. Gen. L. Ch. 93A § 9(1).

656. Under the MCPA, "[a]ny person, who has been injured by another person's use or employment of any method, act or practice" that constitutes "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. L. Ch. 93A §§ 2, 9(1). MCPA § 2(b) provides that these terms are interpreted consistent with Section 5 of the FTC Act (15 U.S.C. § 45(a)), which also prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." Mass. Gen. L. Ch. 93A § 2(b); 15 U.S. § 45(a)(1).

657. Defendants' conduct constitutes an unfair method of competition and unfair and deceptive acts or practices because Defendants' conduct cause Plaintiff and the Class to pay artificially inflated prices for Acthar.

658. Mallinckrodt sold Acthar in Massachusetts under the circumstances and conditions described in this Complaint, and its conduct had a direct and substantial impact on trade and commerce in Massachusetts. Accordingly, such conduct falls within the prohibitions in Ch. 93A § 2.

659. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et seq.

Michigan,
Mich. Stat. § 445.901, *et seq.*

660. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, et seq.

661. Mich. Stat. § 445.901, et seq.

Minnesota
Minn. Stat. § 8.31, *et seq.*

662. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, et seq.

Missouri Merchandising Practices Act ("MMPA"),
Mo. Rev. Stat. 407.020

663. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Missouri Merchandising Practices Act ("MMPA"), Mo. Rev. Stat. 407.020.

664. Under Section 407.020, the MMPA prohibits "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Rev. Stat. 407.020.

665. The Missouri Attorney General has defined an "unfair practice" as:

> any practice which . . . [o]ffends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive decisions; or . . . [i]s unethical, oppressive, or unscrupulous; and . . . [p]resents a risk of, or causes, substantial injury to consumers.

Mo. Att'y Gen. Reg., 15 CSR 60-8.02.

666. Mallinckrodt's conduct constitutes an unfair method of competition and unfair and deceptive acts or practices because Mallinckrodt's conduct caused Plaintiff and the Class to pay artificially inflated prices for Acthar.

Montana,
Mont. Code § 30, 14-101, *et seq*.

667. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30, 14-101, et seq.

Nebraska,
Rev. Stat. § 59-1601, *et seq*.

668. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, et seq.

Nevada,
Nev. Rev. Stat. § 598.0903, *et seq*.

669. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et seq.

New Hampshire,
N.H. Rev. Stat. § 358-A:1, *et seq*.

670. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, et seq.

New Mexico,
N.M. Stat. § 57-12-1, *et seq*.

671. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, et seq.

New York ("Donnelly Act"),
N.Y. Gen. Bus. Law § 349 *et seq*.

672. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 et seq.

North Carolina ("Chapter 75"),
N.C. Gen. Stat. § 75-1.1, *et seq*.

673. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.

North Dakota,
N.D. Cent. Code § 51-15-01, *et seq*.

674. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, et seq.

Ohio,
Ohio Rev. Stat. § 1345.01, *et seq*.

675. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, et seq.

676. Dr. Mandel lives and works in Ohio, along with Mallinckrodt's Chris Sender. The acts and omissions of Dr. Mandel and Mallinckrodt described herein, in addition to those described in the Franks Complaint, demonstrate multiple violations of Ohio law.

Oklahoma
Okla. Stat. 15 § 751, *et seq*.

677. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, et seq.

Oregon
Or. Rev. Stat. § 646.605, *et seq*.

678. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.

Rhode Island
R.I. Gen. Laws § 6-13.1-1, *et seq*.

679. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, et seq.

South Carolina

S.C. Code Laws § 39-5-10, *et seq*.

680. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, et seq.

South Dakota
S.D. Code Laws § 37-24- 1, *et seq*.

681. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24- 1, et seq.

Tennessee
Tenn. Code § 47-18-101, *et seq*.

682. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, et seq.

Texas
Tex. Bus. & Com. Code § 17.41, *et seq*.

683. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.

Utah
Utah Code § 13-11-1, *et seq*.

684. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code § 13-11-1, et seq.

Vermont's Consumer Fraud Act ("Vermont CFA"), Vt. Stat. Ann. tit. 9, § 2451

685. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, et seq.

686. The express statutory purpose of the Vermont CFA is to "protect the public" against "unfair or deceptive acts or practices." Vt. Stat. Ann. tit. 9, § 2451. Its purpose is remedial, and as such the court applies the Act liberally to accomplish its purposes.

687. To establish a "deceptive act or practice" under the Vermont CFA requires three elements: (1) there must be a representation, omission, or practice likely to mislead consumers; (2) the consumer must be interpreting the message reasonably under the circumstances; and (3) the misleading effects must be material, that is, likely to affect the consumer's conduct or decision regarding the product. Vt. Stat. Ann. tit. 9, § 2453(a).

688. Deception is measured by an objective standard, looking to whether the representation or omission had the "capacity or tendency to deceive" a reasonable consumer; actual injury need not be shown. To be reasonable, moreover, the consumer's understanding need not be the only one possible; "if an ad conveys more than one meaning to reasonable consumers and one of those meanings is false, that ad may be condemned." Furthermore, the Act "does not require a showing of intent to mislead, but only an intent to publish the statement challenged."

689. Materiality is also generally measured by an objective standard, premised on what a reasonable person would regard as important in making a decision; it may include a subjective test, however, where the seller knows that the consumer, because of some peculiarity, is particularly susceptible to an omission or misrepresentation.

690. Where the seller knew, or should have known, that an ordinary consumer would need omitted information to evaluate the product or service, or that the claim was false, materiality will be presumed because the manufacturer intended the information or omission to have an effect.

Virginia
Va. Code § 59.1-196, *et seq.*

691. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, et seq.

Washington
Wash. Rev. Code § 19.86.010, *et seq*

692. Mallinckrodt has engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, et seq.

West Virginia
West Virginia Code § 46A-6-101, *et seq.*

693. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, et seq.

WHEREFORE, Steamfitters Local Union No. 420 demands that judgment be entered in its favor and against Mallinckrodt in an amount to be determined at trial, under the consumer fraud laws of these states, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT V
NEGLIGENT MISREPRESENTATION

694. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

695. Defendants' acts violate Pennsylvania common law against negligent misrepresentation, as well as the common law of negligence of other states where members of the Class reside.

696. Negligent misrepresentation requires proof of (1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation.

697. Defendants made misrepresentations of material fact, as detailed herein. For instance, in setting and communicating the AWP-based prices for Acthar, which prices Local

420 paid, the Defendants made material misrepresentations that those prices represented a calculation of real and fact-based prices for their drugs, and that they represented the actual value of the product in the marketplace. Defendants called these prices "average wholesale prices" and when they knew they were not. They did so intending to induce Plaintiff and members of the Class to pay such "average wholesale prices" for Acthar, and Local 420 and the Class in fact, justifiably relied upon such prices in paying them.

698. As set forth herein, Mallinckrodt made multiple misrepresentations about the value of Acthar, in relation to the high prices it set for Acthar. Mallinckrodt knew that these representations were false, yet they made them intending to induce payors like Plaintiff and the Class to pay for Acthar. Plaintiff and the Class, in fact, justifiably relied on such statements of value, as Acthar was placed on lists of "specialty" drugs, by pharmacy benefits managers, like Future Scripts, for which deep discounts on brands and generics were unavailable.

699. These representations were material to the transactions at hand in that Local 420 used and relied upon the inflated prices for Acthar as the basis for the amount to pay and/or reimburse for Acthar under the specialty drug provisions of its agreements with IBC and Future Scripts.

700. Defendants knew or should have known of the falsity of their misrepresentations, especially as to the purported value of Acthar. Mallinckrodt bought Acthar for $100,000 when it was selling for only $40. Having spoken about the purported value of Acthar in relation to is high pricing Mallinckrodt and its KOLs had a duty to speak the truth about the lack of value for new indications.

701. As set forth more fully above, the prices communicated by Defendants to payors like Plaintiff through the ASAP and UBC HUB were artificial prices, unrelated to any actual,

reasonable price in the marketplace, or actual value of Acthar. Instead, they were intentionally created and manipulated by the Defendants for the purpose of generating exorbitant revenue, thus constituting false representations which the Defendants knew or, in the absence of recklessness, should have known to be false.

702. The Defendants made these misrepresentations about the actual prices for and value of Acthar with the intent of misleading Local 420 and the Class into relying on the prices as real and fact-based prices, rather than artificially inflated prices.

703. Local 420 and the Class justifiably relied upon these false misrepresentations in purchasing and/or reimbursing Acthar at the amount charged by Mallinckrodt through its ASAP and HUB based on the prices it set in 2007 and beyond. As a result, Plaintiff was injured by paying more for Acthar than it should have.

704. The Pennsylvania Supreme Court has expressly adopted several aspects of the Restatement (Second) of Torts relevant to the claims of Plaintiff ad the Class. For instance, Section 552, which is titled "Information Negligently Supplied for the Guidance of Others", provides, in pertinent part: (1) one who, in the course of his business, profession, or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information. (2) …[T]he liability stated in (1) is limited to loss suffered (a) by the person or one of a limited group of persons for whose benefit and guidance he intends to supply the information or knows that the recipient intends to supply it; and (b) through reliance upon it in a transaction that he intends the information to influence or

knows that the recipient so intends or in a substantially similar transaction." *Bitt-Rite Contrs, Inc., v. Architectural Studio*, 581 Pa. 454, 459 n.1, 866 A.2d. 270 (2005).

705. Here, Mallinckrodt and UBC are "expert suppliers of information" about Acthar which information is widely disseminated to the public in general, and the medical community in particular, in order to induce justifiable reliance on the information being supplied. They hold themselves out to the public as such experts. Mallinckrodt is the manufacturer of Acthar, and an expert to whom patients (like the Plaintiff's-beneficiary who took Acthar), payers (like Plaintiff and the Class), doctors (like the prescribers of the Acthar here), PBMs (like Express Scripts) and others look for information about value, pricing and safety of its drugs.

706. UBC is a self-described "HUB" of information about Acthar, its uses, benefits and prices. It is the Mallinckrodt's designated interface between the providers, patients, and third party payors, as well as the manufacturer. Mallinckrodt trains UBC RSs about Acthar, which information UBC then shares with patients, payors and providers.

707. Mallinckrodt and UBC supplied information described herein "in the course of [their] business, profession, or employment". They supplied misleading and deceptive information for the guidance of the Local 420 patients and the Plaintiff itself, as well as the Class, in course of business transactions involving the distribution, sales and payment for Acthar. Plaintiff and the Class justifiably relied on such information in paying the high prices for Acthar being charged in 2018.

708. Mallinckrodt and UBC failed to exercise reasonable care or competence in the promulgation of misleading and deceptive information about the value of Acthar, as evidenced by Express Scripts' 2017 revelations that Acthar was not worth what was being charged for it. Plaintiff and the Class are entitled to recover for their losses suffered, since Local 420 and its

beneficiary, as well as the Class of third party payors, are persons for whose benefit and guidance Defendants intended to supply the information of Acthar value and the Defendants knew or should have known Local 420 and its beneficiary, as well as the Class, would receive such information and rely upon it.

709. As a direct and proximate result of the misrepresentations of Mallinckrodt, as set forth above, Local 420 and the Class were harmed in that they justifiably relied on the negligent misrepresentations about the value of Acthar in relation to its high prices.

710. Plaintiff and the Class were unaware of the artificial, inflated prices of Acthar, and would not have paid and/or reimbursed the artificially inflated prices for Acthar had they known of the misrepresentations of material fact made by Defendants. Plaintiff and the Class overpaid for the Acthar because of such misrepresentations.

WHEREFORE, Steamfitters Local Union No. 420 demands that judgment be entered in its favor, and in favor of the Class, and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VI
AIDING AND ABETTING/CONSPIRACY

711. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

712. As set forth more fully above, beginning at least as early as 2007, the exact date being unknown to the Plaintiff and the Class, and continuing thereafter until the present, Defendants and other unnamed co-conspirators (including providers who acted as KOLs for Defendants), between and among themselves and others, entered into an agreement and/or otherwise engaged in a continuing conspiracy to defraud and deceive the Plaintiff and the Class

by causing it to pay more for Acthar than it otherwise would have paid in the absence of the Defendants' conspiracy and concerted action.

713. Pursuant to the unfair and deceptive schemes to distribute, price and market Acthar at high prices, which bore no reasonable relation to the value of the drug as ascribed to it in 2017 by Express Scripts, and the conspiracy alleged herein, and in furtherance thereof, Defendants and their co-conspirators engaged in a wide range of activities, the purpose and effect of which was to defraud, deceive and misinform Local 420 and the Class as to the truth about Acthar pricing and value, and acted or took substantial steps in furtherance of the conspiracy. Those acts include the following:

a. discussing and agreeing among themselves and with their co-conspirators that they would control and communicate the price at which Local 420 and the Class paid for Acthar far above the reasonable value of the drug;

b. discussing and agreeing among themselves and with their co-conspirators that they would increase the price at which Local 420 and the Class paid for Acthar;

c. discussing and agreeing among themselves and with their co-conspirators that they would jointly implement and directly control the ASAP program, and associated materials and website, which enrolled patients into an exclusive distribution network for the administration of Acthar, allowing Defendants to raise the prices unchecked and to conduct their unfair pricing scheme for Acthar;

d. discussing and agreeing among themselves and with their co-conspirators that they would directly control the exclusive distribution network for Acthar through the ASAP Program and the UBC "HUB",

e. discussing and agreeing among themselves and with their co-conspirators that they would rely on employees to promote the ASAP Program through the marketing alleged herein;

f. discussing and agreeing among themselves and with their co-conspirators that they would conceal and suppress the truth about the Acthar inflated prices, the Acthar true value, and the monies

earned from payors like Local 420 and the Class.

714. In addition to the specific facts set forth above, it is alleged the Defendants and their co-conspirators engaged in conspiratorial meetings, among the purposes of which meetings were to discuss the importance of controlling the direct distribution, marketing, sale and administration of Acthar to payors like Local 420 and the Class, and deriving substantial profits from these activities. These meetings took place in the summer of 2007, when Defendants were negotiating the contracts that form their exclusive agreement. The meetings and communications continued thereafter when Mallinckrodt and UBC agreed to raise the prices for Acthar to its current exorbitant levels, and communicate those inflated prices to patients and TPPs. They have also taken place after Relators sued.

715. There was a common design pursuant to which Defendants carried out their tortious acts of negligently misrepresenting the truth about Acthar, and the acts or practices in violation of the consumer fraud laws. The common designed involved, among other things, misleading patients and payors, like Plaintiff and the Class, about the value of Acthar in relation to its high prices, and concealing the truth about Acthar and their exclusive arrangements.

716. There was a common design pursuant to which Defendants carried out their tortious acts of negligently misrepresenting the truth about Acthar and their exclusive arrangements, and the acts or practices in violation of the consumer fraud laws. The common design involved, among other things, misleading patients and payors, like Plaintiff and the Class, about the value of Acthar in relation to its high prices, and concealing the truth about Acthar and their exclusive arrangements.

717. Here, Mallinckrodt aided and abetted its sales representatives, including MSLs, and multiple doctors engaged as KOLs in unlawful acts, practices, misrepresentations, omissions

and deception, knowing that they were breaching their duty to tell the truth, having spoken publicly about Acthar, its uses and benefits, and its price. Mallinckrodt aided and abetted providers in breaching their obligations to patients covered by Plaintiff and the Class by continuing to conceal and suppress the truth about Acthar's lack of value. Mallinckrodt gave substantial assistance to sales representatives and KOLs in accomplishing their tortious conduct, and their conduct in so assisting, breached a separate duty owed to the Plaintiff and the Class.

718. UBC aided and abetted Mallinckrodt in their schemes by serving as the HUB and direct interface with patients and payors to ensure that Acthar prescriptions were filled and paid for at inflated AWPs as set by Mallinckrodt.

719. The Defendants performed the conspiratorial acts set forth herein intending to injure payors of Acthar, like Local 420 and the Class, by causing them to pay inflated prices so that the Defendants could derive substantial profits.

720. The Defendants performed the acts alleged herein in furtherance of the common plan or design for the conspiracy with intent and/or with knowledge of the injury and damage it would cause to Local 420 and the Class, and with knowledge and intent to cause such injuries and/or with reckless disregard for the consequences. These acts were either unlawful (as in the case of the acts described in Counts I, II and III) or lawful by an unlawful means as for an unlawful purpose (as in the case of Defendants' willful silence in the face of its co-conspirators' misinformation and misrepresentations).

721. As a direct and proximate result of the Defendants' conspiracy and aiding and abetting as alleged herein, Local 420 and the Class have been injured and damaged, and the Defendants are jointly and severally liable for such injuries and damages.

WHEREFORE, Steamfitters Local Union No. 420 demands that judgment be entered in

its favor, and in favor of the Class and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VII
UNJUST ENRICHMENT

722. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

723. This Count alleges unjust enrichment against Mallinckrodt.

724. Like the beneficiaries in the Class, Local 420's covered beneficiary received direct shipments of Acthar from Mallinckrodt via its exclusive distribution mechanism established with CuraScript and UBC. In exchange for such Acthar, Local 420 and the Class made payments to Mallinckrodt, through UBC. The amount charged by Mallinckrodt for Acthar was the amount paid by Local 420 and the Class pursuant to their agreements with their healthcare plans.

725. The amounts paid by Local 420 and the Class were valuable to Mallinckrodt and UBC, and both Mallinckrodt and UBC were unjustly enriched by such payments, in that, the reimbursement rates charged by Mallinckrodt were valuable and beneficial to Mallinckrodt, and Mallinckrodt compensated UBC out of such funds.

726. By engaging in the conduct described herein, Mallinckrodt and UBC have knowingly obtained benefits from Local 420 and the Class, namely, grossly inflated revenue from their direct involvement in coordinating all aspects of the receipt of and payments for Acthar, under circumstances such that it would be inequitable and unjust for Mallinckrodt and UBC to retain such benefits.

727. Mallinckrodt and UBC were able to extract exorbitant revenue from Local 420 and the Class beyond what either could have received in the absence of their unlawful conduct. This conduct violated the consumer protection laws of Pennsylvania and other states, as well as the common laws of Pennsylvania and other states, and, as such, interfered with the legally protected interests of Local 420 and the Class.

728. Local 420 and each member of the Class are therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies derived by the Defendants by means of the above-described actions.

729. By engaging in the unlawful conduct described herein, Mallinckrodt and UBC have been knowingly enriched by the amount charged for Acthar over and above what they could have charged in a competitive market.

WHEREFORE, Steamfitters Local Union No. 420 demands that judgment be entered in its favor, and in favor of the Class, and against Mallinckrodt, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VIII
DECLARATORY AND INJUNCTIVE RELIEF

730. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

731. Plaintiff has alleged an interest which, insofar as it paid inflated prices for Acthar, is substantial and immediate insofar as it has had to pay exorbitant prices for Acthar in 2018. There is a reasonable likelihood that Plaintiff will have to pay for Acthar in the future, especially given Mallinckrodt's and UBC's marketing efforts to expand Acthar prescriptions into new indications, like the rheumatic disorder suffered by its beneficiary.

732. Thus, Plaintiff has alleged a real, actual controversy with Defendants that requires immediate attention. The public has already shown an interest in the Acthar lawsuit being litigated in Rockford, Illinois. Thus, Plaintiff's request for declaratory and injunctive relief does not seek merely an abstract or advisory opinion.

733. Plaintiff and the Class hereby request that the acts and practices set forth herein be declared unlawful under the consumer fraud laws and/or the common law of negligent misrepresentation, regardless of the quantum of damages suffered individually by Plaintiff and the Class, the precise calculation of which will have to await discovery. This will inure to the benefit of Plaintiff, its beneficiaries, the members of the coalition of which Plaintiff is a part, and self-funded payors, everywhere in the Class who have paid, are paying, or will pay in the future for Acthar.

734. Plaintiff and the Class also request the issuance of an injunction to enjoin Mallinckrodt and UBC from conspiring and agreeing to raise the prices of Acthar above competitive levels, and from charging such inflated prices. The injunction should also prohibit Mallinckrodt and UBC from engaging in the unlawful practices alleged herein.

735. An injunction is needed to prevent immediate and irreparable harm that cannot be compensated adequately by damages. Plaintiff and the Class will be irreparably harmed if an injunction does not timely issue because patients are put at risk as payors like Plaintiff and the Class are forced to decide about whether to cover all the new indications for which Mallinckrodt and UBC are marketing Acthar. Further, because multiple, individual actions would be required to bring about what one injunction in this action could accomplish, there is an inadequate legal remedy. Plaintiff has no adequate remedy at law to prevent Defendants from furthering acting to

harm itself and its patient-beneficiaries due to the unchecked nature of their pricing decisions, which have been demonstrated to be far above any reasonable "value" assessment.

736. Greater injury would result from refusing the injunction than from granting it, as patients and payors like Plaintiff will continue to be threatened by new prescriptions of Acthar at exorbitant price levels, threatening patient care. The issuance of an injunction will not substantially harm Mallinckrodt or UBC, because Mallinckrodt and UBC will continue to sell Acthar for all the approved indications, albeit at lower prices.

737. The injunction will properly restore the parties to where they were before the unlawful conduct was begun by Defendants.

738. Plaintiff has a clear right to relief and is likely to prevail on the merits, which this case is related to and which at least Mallinckrodt has indicated a willingness to settle rather than fight.

739. The injunction, as will be framed in an appropriate motion to the court, will be reasonably suited to abate the offending activity only.

740. The public interest will not by adversely affected by the injunction. To the contrary, the public interest will be served by stopping the unlawful practices by Mallinckrodt.

741. All the requisite elements for issuance of an injunction have been, and will be, met.

PRAYER FOR RELIEF

WHEREFORE, Steamfitters Local Union No. 420 and the Class request the Court to enter the following relief:

a. Declare unlawful the acts and practices alleged herein, enjoin Mallinckrodt from committing the acts alleged herein, and restore the status quo before the unlawful conduct took place;

b. Enter judgment Mallinckrodt and UBC for the violations alleged herein;

c. Certify a Class of all third party payors and their beneficiaries;

d. Award the actual damages incurred by Plaintiff and the Class as a result of the wrongful acts complained of, along with pre-judgment and post-judgment interest at the maximum rate allowed by law;

e. Award statutory damages set forth herein under the statutory claims alleged;

f. Award treble damages or multiple damages by operation of law;

g. Award punitive damages;

h. Award Plaintiff and the Class the costs of this action, including reasonable attorney's fees, and, where applicable, expert fees; and

i. Award such other and further relief as the Court may deem just and appropriate.

JURY DEMAND

Steamfitters Local Union No. 420 and the Class hereby demand a trial by jury of all issues so triable in this cause.

Respectfully submitted,

Date: July 12, 2019

By: */s/ Donald E. Haviland, Jr*

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(PA ID No. 66616)
William H. Platt II, Esquire
(PA ID No. 83585)
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Counsel for Plaintiff,
Steamfitters Local Union No. 420 and the Class

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
STEAMFITTERS LOCAL UNION NO. 420
14420 Townsend Road
Philadelphia, PA 19154

(b) County of Residence of First Listed Plaintiff Philadelphia
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Donald E. Haviland, Jr. / William H. Platt II
Haviland Hughes
201 S. Maple Way, Suite 110, Ambler, PA 19002 (215) 609-4661

DEFENDANTS
MALLINCKRODT ARD, INC. formerly known as Questcor Pharmaceuticals, Inc.
(see attached sheet for additional defendants)

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated or Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for Nature of Suit Code Descriptions

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☒ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*
Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d)
Brief description of cause:
Unfair and Deceptive Marketing and Sales Practices

VII. REQUESTED IN COMPLAINT:
☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
DEMAND $ Over $5 million
CHECK YES only if demanded in complaint
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*
JUDGE Hon. Berle M. Schiller DOCKET NUMBER 2:12-cv-00175

DATE 7/12/19 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

JS 44 Reverse (Rev. 06/17)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.)**

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

STEAMFITTERS LOCAL UNION NO. 420	:	CIVIL ACTION
v.	:	
MALLINCKRODT ARD, INC., et al	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

7/12/2019	Donald E. Haviland, Jr., Esq.	Plaintiff
Date	**Attorney-at-law**	**Attorney for**
215-609-4661	215-392-4400	haviland@havilandhughes.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

Civil Justice Expense and Delay Reduction Plan
Section 1:03 - Assignment to a Management Track

(a) The clerk of court will assign cases to tracks (a) through (d) based on the initial pleading.

(b) In all cases not appropriate for assignment by the clerk of court to tracks (a) through (d), the plaintiff shall submit to the clerk of court and serve with the complaint on all defendants a case management track designation form specifying that the plaintiff believes the case requires Standard Management or Special Management. In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a case management track designation form specifying the track to which that defendant believes the case should be assigned.

(c) The court may, on its own initiative or upon the request of any party, change the track assignment of any case at any time.

(d) Nothing in this Plan is intended to abrogate or limit a judicial officer's authority in any case pending before that judicial officer, to direct pretrial and trial proceedings that are more stringent than those of the Plan and that are designed to accomplish cost and delay reduction.

(e) Nothing in this Plan is intended to supersede Local Civil Rules 40.1 and 72.1, or the procedure for random assignment of Habeas Corpus and Social Security cases referred to magistrate judges of the court.

SPECIAL MANAGEMENT CASE ASSIGNMENTS
(See §1.02 (e) Management Track Definitions of the Civil Justice Expense and Delay Reduction Plan)

Special Management cases will usually include that class of cases commonly referred to as "complex litigation" as that term has been used in the Manuals for Complex Litigation. The first manual was prepared in 1969 and the Manual for Complex Litigation Second, MCL 2d was prepared in 1985. This term is intended to include cases that present unusual problems and require extraordinary treatment. See §0.1 of the first manual. Cases may require special or intense management by the court due to one or more of the following factors: (1) large number of parties; (2) large number of claims or defenses; (3) complex factual issues; (4) large volume of evidence; (5) problems locating or preserving evidence; (6) extensive discovery; (7) exceptionally long time needed to prepare for disposition; (8) decision needed within an exceptionally short time; and (9) need to decide preliminary issues before final disposition. It may include two or more related cases. Complex litigation typically includes such cases as antitrust cases; cases involving a large number of parties or an unincorporated association of large membership; cases involving requests for injunctive relief affecting the operation of large business entities; patent cases; copyright and trademark cases; common disaster cases such as those arising from aircraft crashes or marine disasters; actions brought by individual stockholders; stockholder's derivative and stockholder's representative actions; class actions or potential class actions; and other civil (and criminal) cases involving unusual multiplicity or complexity of factual issues. See §0.22 of the first Manual for Complex Litigation and Manual for Complex Litigation Second, Chapter 33.

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM
(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 14420 Townsend Road, Philadelphia PA 19154

Address of Defendant: 1425 U.S. Route 206, Bedminster NJ. 07921

Place of Accident, Incident or Transaction: Philadelphia PA

RELATED CASE, IF ANY:

Case Number: 2:12-cv-00175 Judge: Hon. Berle M. Schiller Date Terminated: _____

Civil cases are deemed related when *Yes* is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes ☐ No ☐
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes ☐ No ☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court? Yes ☐ No ☐
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes ☐ No ☐

I certify that, to my knowledge, the within case ☑ **is** / ☐ **is not** related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: July 12, 2019 _____ 83585
Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

CIVIL: (Place a √ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Patent
- ☐ 6. Labor-Management Relations
- ☐ 7. Civil Rights
- ☐ 8. Habeas Corpus
- ☐ 9. Securities Act(s) Cases
- ☐ 10. Social Security Review Cases
- ☑ 11. All other Federal Question Cases *(Please specify):* RICO

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury *(Please specify):* _____
- ☐ 7. Products Liability
- ☐ 8. Products Liability – Asbestos
- ☑ 9. All other Diversity Cases *(Please specify):* RICO

ARBITRATION CERTIFICATION
(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Owen H. Rath, II, counsel of record *or* pro se plaintiff, do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs:

☒ Relief other than monetary damages is sought.

DATE: July 12, 2019 _____ 83585
Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

Civ. 609 (5/2018)

EXHIBIT A

PRO

H.P. Acthar GEL
(repository corticotropin injection) 80 U/mL

☐ SENT PRESCRIPTION DIRECTLY TO SPECIALTY PHARMACY. PLEASE ENROLL PATIENT IN HUB SERVICES.

PHARMACY NAME: _____

FAX: 1-877-937-2284
Acthar Start Form
Please complete Start Form and fax toll-free
TEL: 1-888-435-2284
Monday through Friday (8:00 AM to 9:00 PM ET)
Saturday (9:00 AM to 2:00 PM ET)

1. PATIENT INFORMATION
Patient has been notified of referral ☐ YES ☐ NO

PATIENT FIRST NAME | PATIENT MIDDLE INITIAL | PATIENT LAST NAME | DATE OF BIRTH | GENDER

HOME ADDRESS | CITY | STATE | ZIP

SHIPPING ADDRESS (IF NOT HOME ADDRESS) | CARE OF (IF NOT ADDRESSED TO PATIENT) | CITY | STATE | ZIP

HOME PHONE | MOBILE | ☐ OK TO TEXT | BEST TIME TO CALL

EMAIL ADDRESS | PREFERRED LANGUAGE IF NOT ENGLISH

ALTERNATIVE CONTACT NAME | RELATIONSHIP TO PATIENT | TELEPHONE

2. INSURANCE INFORMATION (PLEASE INCLUDE COPIES OF CARDS)

PHARMACY BENEFITS | SUBSCRIBER ID # | GROUP # | TEL #

PRIMARY MEDICAL INSURANCE | SUBSCRIBER ID # | GROUP # | TEL #

3. HEALTHCARE PROVIDER (HCP) INFORMATION

HCP FIRST NAME | HCP LAST NAME | HCP MIDDLE INITIAL | NPI # | GROUP NPI # (IF APPLICABLE) | STATE LICENSE #

SPECIALTY: ☐ PULMONOLOGY ☐ RHEUMATOLOGY ☐ OPHTHALMOLOGY ☐ OTHER (PLEASE INDICATE) _____

FACILITY NAME | TELEPHONE | FAX

ADDRESS | CITY | STATE | ZIP

OFFICE CONTACT NAME | CONTACT TELEPHONE | MOBILE NUMBER | EMAIL ADDRESS

PREFERRED METHOD OF COMMUNICATION: ☐ OFFICE PHONE ☐ MOBILE PHONE ☐ FAX ☐ EMAIL ☐ TEXT ☐ NO PREFERENCE

4. PRESCRIPTION: H.P. ACTHAR® GEL
NDC# 63004-8710-1 5 mL multidose vial containing 80 USP units per mL

PRIMARY DIAGNOSIS CODES ON PAGE 2, SECTION 6

ICD-10 CODE: _____

DOSE: _____ ☐ UNITS ☐ mL | ROUTE OF ADMINISTRATION ☐ INTRAMUSCULAR ☐ SUBCUTANEOUS | SCHEDULE/FREQUENCY: _____ | QUANTITY OF 5 mL MULTIDOSE VIALS: _____ REFILLS: _____

ALLERGIES _____ ADDITIONAL SPECIAL INSTRUCTIONS, TITRATION OR TAPER DOSE, IF APPLICABLE:

IDENTIFYING SUPPLIES IS MANDATORY FOR A COMPLETE PRESCRIPTION:

SYRINGE SIZE: ☐ 1 mL ☐ 3 mL ☐ Other size _____ QUANTITY: ☐ 1 box of 100 ☐ Other: _____

NEEDLE SIZE FOR DRAWING: ☐ 18 G needle, 1" ☐ Other: _____ QUANTITY: ☐ 1 box of 100 ☐ Other: _____

NEEDLE SIZE FOR INJECTION: ☐ 25 G needle, 1" *(Intramuscular)* ☐ 25 G needle, 5/8" *(Subcutaneous)* ☐ Other: _____ QUANTITY: ☐ 1 box of 100 ☐ Other: _____

SUPPLY REFILLS: _____ SHARPS CONTAINER: _____

ACTHAR INJECTION TRAINING SERVICES

By initialing here (original required), I request that company-funded Acthar Injection Training Services be arranged for my patient. I understand that Acthar Injection Training Services are for one instruction visit only and NOT a home health nursing service. I also understand that all reasonable efforts will be made to schedule the Acthar Injection Training Services visit within 24 hours of the patient's receipt of drug shipment. Patients can contact their Case Manager at any time about Injection Training.

▶ _____
HEALTHCARE PROVIDER'S INITIALS DATE

5. PRESCRIPTION, CONSENT, AND STATEMENT OF MEDICAL NECESSITY: HCP SIGNATURE REQUIRED

I certify that H.P. Acthar® Gel is medically necessary for this patient and that I have reviewed this therapy with the patient and will be monitoring the patient's treatment. I verify that the patient and healthcare provider information on this enrollment form was completed by me or at my direction and that the information contained herein is complete and accurate to the best of my knowledge. I understand that I must comply with my practicing state's specific prescription requirements, such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements could result in outreach to me by the dispensing pharmacy.

I authorize United BioSource LLC ("UBC"), the current operator of the Acthar Hub, and other designated operators of the Program to perform a preliminary assessment of benefit verification for this patient and furnish information requested by the patient's insurer that is available on this form. I understand that insurance verification is ultimately the responsibility of the provider and that third-party reimbursement is affected by a variety of factors. While UBC tries to provide accurate information, they and Mallinckrodt make no representations or warranties as to the accuracy of the information provided.

I understand that representatives from the Program or UBC may contact me or my patient for additional information relating to this prescription. I acknowledge and agree that the designated Specialty Pharmacy receive this prescription via a designated third party, the Program, and that no additional confirmation of receipt of prescription is required by the designated Specialty Pharmacy.

HCP Prescriber Signature - Please sign ONE LINE below

▶ _____ **OR** ▶ _____
DISPENSE AS WRITTEN DATE SUBSTITUTIONS ALLOWED DATE

Prescriber signature required for consent and to validate prescriptions. Prescriber attests that this is her/his signature. NO STAMPS. By signing, prescriber certifies that the above is medically necessary.

H.P. Acthar GEL
(repository corticotropin injection) 80 U/mL

Patient Name:_____ **Date of Birth:**_____

6. DIAGNOSIS AND MEDICAL INFORMATION

Diagnosis Codes

Please check the diagnosis code that corresponds with the patient's condition. Below is a list of common ICD-10 codes and you may also write the patient's diagnosis in the "OTHER" section.

PULMONOLOGY

- ❑ SARCOIDOSIS **D86**
- ❑ SARCOIDOSIS OF LUNG **D86.0**
- ❑ SARCOIDOSIS OF LYMPH NODES **D86.1**
- ❑ SARCOIDOSIS OF LUNG WITH SARCOIDOSIS OF LYMPH NODES **D86.2**
- ❑ SARCOIDOSIS OF SKIN **D86.3**
- ❑ SARCOIDOSIS OF OTHER SITES **D86.8**
- ❑ SARCOID MENINGITIS **D86.81**
- ❑ MULTIPLE CRANIAL NERVE PALSIES IN SARCOIDOSIS **D86.82**
- ❑ SARCOID IRIDOCYCLITIS **D86.83**
- ❑ SARCOID PYELONEPHRITIS **D86.84**
- ❑ SARCOID MYOCARDITIS **D86.85**
- ❑ SARCOID ARTHROPATHY **D86.86**
- ❑ SARCOID MYOSITIS **D86.87**
- ❑ SARCOIDOSIS OF OTHER SITES **D86.89**
- ❑ SARCOIDOSIS, UNSPECIFIED **D86.9**

RHEUMATOLOGY

- ❑ ARTHROPATHIC PSORIASIS, UNSPECIFIED **L40.50**
- ❑ OTHER PSORIATIC ARTHROPATHY **L40.59**
- ❑ RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF MULTIPLE SITES WITHOUT ORGAN OR SYSTEMS INVOLVEMENT **M05.79**
- ❑ RHEUMATOID ARTHRITIS, UNSPECIFIED **M06.9**
- ❑ SYSTEMIC LUPUS ERYTHEMATOSUS, ORGAN OR SYSTEM INVOLVEMENT UNSPECIFIED **M32.10**
- ❑ GLOMERULAR DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS **M32.14**
- ❑ SYSTEMIC LUPUS ERYTHEMATOSUS, UNSPECIFIED **M32.9**
- ❑ OTHER DERMATOMYOSITIS WITH MYOPATHY **M33.12**
- ❑ POLYMYOSITIS, ORGAN INVOLVEMENT UNSPECIFIED **M33.20**
- ❑ POLYMYOSITIS WITH MYOPATHY **M33.22**

OPHTHALMOLOGY

- ❑ NEUROMYELITIS OPTICA [DEVIC] **G36.0**
- ❑ UNSPECIFIED SCLERITIS, UNSPECIFIED EYE **H15.009**
- ❑ SCLERITIS WITH CORNEAL INVOLVEMENT, RIGHT EYE **H15.041**
- ❑ UNSPECIFIED SUPERFICIAL KERATITIS, BILATERAL **H16.103**
- ❑ FILAMENTARY KERATITIS, BILATERAL **H16.123**
- ❑ PUNCTATE KERATITIS, RIGHT EYE **H16.141**
- ❑ PUNCTATE KERATITIS, LEFT EYE **H16.142**
- ❑ PUNCTATE KERATITIS, BILATERAL **H16.143**
- ❑ OTHER KERATOCONJUNCTIVITIS, BILATERAL **H16.293**
- ❑ UNSPECIFIED INTERSTITIAL KERATITIS, RIGHT EYE **H16.301**
- ❑ OTHER KERATITIS **H16.8**
- ❑ PRIMARY IRIDOCYCLITIS, LEFT EYE **H20.012**
- ❑ RECURRENT ACUTE IRIDOCYCLITIS, LEFT EYE **H20.022**
- ❑ SECONDARY NONINFECTIOUS IRIDOCYCLITIS, RIGHT EYE **H20.041**
- ❑ CHRONIC IRIDOCYCLITIS, RIGHT EYE **H20.11**
- ❑ CHRONIC IRIDOCYCLITIS, LEFT EYE **H20.12**
- ❑ CHRONIC IRIDOCYCLITIS, BILATERAL **H20.13**
- ❑ UNSPECIFIED IRIDOCYCLITIS **H20.9**
- ❑ UNSPECIFIED CHORIORETINAL INFLAMMATION, BILATERAL **H30.93**
- ❑ RETINAL VASCULITIS, BILATERAL **H35.063**
- ❑ PANUVEITIS, RIGHT EYE **H44.111**
- ❑ PANUVEITIS, LEFT EYE **H44.112**
- ❑ PANUVEITIS, BILATERAL **H44.113**
- ❑ SYMPATHETIC UVEITIS, UNSPECIFIED EYE **H44.139**
- ❑ RETROBULBAR NEURITIS, RIGHT EYE **H46.11**
- ❑ RETROBULBAR NEURITIS, LEFT EYE **H46.12**
- ❑ OTHER OPTIC NEURITIS **H46.8**
- ❑ UNSPECIFIED OPTIC NEURITIS **H46.9**
- ❑ OTHER IRREGULAR EYE MOVEMENTS **H55.89**
- ❑ Other: _____

ORGAN INVOLVEMENT

- ❑ LUNGS
- ❑ LYMPH NODES
- ❑ SKIN AND TISSUES
- ❑ EYES
- ❑ HEART
- ❑ BRAIN AND NERVOUS SYSTEM
- ❑ BONES, JOINTS, CARTILAGE, LIGAMENTS, TENDONS AND MUSCLES
- ❑ SPLEEN
- ❑ LIVER
- ❑ KIDNEYS AND URINARY TRACT
- ❑ SALIVARY GLANDS
- ❑ SINUSES
- ❑ OTHER:

7. HISTORY OF CORTICOSTEROID USE (IF APPLICABLE) PLEASE ADD DETAILS IN SECTION 9 BELOW.

Please check all that apply:

A corticosteroid **was** tried with the following response(s):

- ❑ Corticosteroid use failed, but same response not expected with Acthar
- ❑ Patient hypersensitive or allergic to corticosteroids
- ❑ Patient intolerant of corticosteroids
- ❑ Other: _____

OR

A corticosteroid **was not** tried due to the following response(s):

- ❑ Corticosteroid use is contraindicated for this patient
- ❑ Intravenous access is not possible for this patient
- ❑ Patient has known intolerance to corticosteroids
- ❑ Other: _____

8. CONCURRENT MEDICATIONS

9. RELEVANT TREATMENT HISTORY (INCLUDING RECENT STEROID HISTORY. ATTACH ADDITIONAL PAGES AS NECESSARY.)

Therapy Name	Dose	Start Date	Stop Date (if applicable)	Explain Outcome With Detail (eg, type of outcome)

OTHER RELEVANT CLINICAL INFORMATION

HCP SIGNATURE: REQUIRED FOR DOCUMENTATION

I verify that the patient and healthcare provider information on this enrollment form was completed by me or at my direction and that the information contained herein is complete and accurate to the best of my knowledge. I certify that my patient has agreed in writing to be contacted by Program administrators or UBC and be furnished with Program or other information or materials.

NAME _____ SIGNATURE _____ DATE _____

H.P. Acthar GEL
(repository corticotropin injection) 80 U/mL

Completion by patient or their representative

Patient Name:_____ **Date of Birth:**_____

10. PATIENT AUTHORIZATION(S)

Patient Consent to allow Acthar Support Team to work together with your insurance provider, pharmacy, advocacy organization and others to provide support on your behalf.

By signing this authorization, I authorize my physician(s), my health insurance company and my pharmacy providers (collectively, "Designated Parties") to disclose to Mallinckrodt ARD Inc. ("Mallinckrodt"), the distributor of Acthar, and its agents, authorized designees and contractors, including Mallinckrodt reimbursement support personnel and United BioSource LLC ("UBC") or any other operator of the Acthar Hub on behalf of Mallinckrodt (collectively, "Manufacturer Parties"), health information relating to my medical condition, treatment and insurance coverage (my "Health Information") in order for them to (1) provide certain services to me, including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injection training, (2) provide me with support services and information associated with my Acthar therapy, (3) serve internal business purposes, such as marketing research, internal financial reporting and operational purposes, and (4) carry out the Manufacturer Parties' respective legal responsibilities.

Once my Health Information has been disclosed to Manufacturer Parties, I understand that it may be redisclosed by them and no longer protected by federal and state privacy laws. However, Manufacturer Parties agree to protect my Health Information by using and disclosing it only for the purposes detailed in this authorization or as permitted or required by law.

I understand that I may refuse to sign this authorization and that my physician and pharmacy will not condition my treatment on my agreement to sign this authorization form, and my health plan or health insurance company will not condition payment for my treatment, insurance enrollment or eligibility for insurance benefits on my agreement to sign this authorization form. I understand that my pharmacies and other Designated Parties may receive payment in connection with the disclosure of my Health Information as provided in this authorization. I understand that I am entitled to receive a copy of this authorization after I sign it.

I may revoke (withdraw) this authorization at any time by mailing a letter to the Acthar Hub, 255 Technology Park, Lake Mary, FL 32746. Revoking this authorization will end further disclosure of my Health Information to Manufacturer Parties by my pharmacy, physicians, and health insurance company when they receive a copy of the revocation, but it will not apply to information they have already disclosed to Manufacturer Parties based on this authorization. I also know I may cancel my enrollment in a patient support program at any time in writing by contacting Mallinckrodt via fax at 1-877-937-2284 or by calling the Acthar Hub at 1-888-435-2284. This authorization is in effect for 5 years unless a shorter period is provided for by state law or until the conclusion of any ongoing coverage support, whichever is longer, once I have signed it unless I cancel it before then.

THIS SECTION MUST BE COMPLETED IN ITS ENTIRETY, INCLUDING DATE

▶ _____ _____ _____ _____

PATIENT NAME OR LEGAL REPRESENTATIVE | PATIENT SIGNATURE | IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT | DATE

Patient Consent to receive additional information from Mallinckrodt such as education on your disease and Acthar.

I authorize Mallinckrodt and its partners to use, disclose, and/or transfer the personal information I supply (1) to contact me and provide me with informational and marketing materials and clinical trial opportunities related to my condition or treatment by any means of communication, including but not limited to text, email, mail, or telephone; (2) to help Mallinckrodt improve, develop, and evaluate products, services, materials, and programs related to my condition or treatment; (3) to enroll me in and provide me with Acthar-related programs and services that I may select or refuse at any time; (4) to disclose my enrollment and use of these services to my healthcare providers and insurers; and (5) to use my information that cannot identify me for scientific and market research. This authorization will remain in effect until I cancel it, which I may do at any time in writing by contacting Mallinckrodt via fax at 1-877-937-2284 or by calling the Acthar Hub at 1-888-435-2284. I may request a copy of this signed authorization.

▶ _____ _____ _____ _____

PATIENT NAME OR LEGAL REPRESENTATIVE | PATIENT SIGNATURE | IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT | DATE

If patient is not present to sign the form, send them to
ActharConsent.com
and have them sign electronically.

RESOURCE PAGE. DO NOT NEED TO FAX BACK.

RHEUMATOLOGY

ARTHROPATHIC PSORIASIS, UNSPECIFIED
L40.50

DISTAL INTERPHALANGEAL PSORIATIC ARTHROPATHY
L40.51

PSORIATIC ARTHRITIS MUTILANS
L40.52

PSORIATIC SPONDYLITIS
L40.53

PSORIATIC JUVENILE ARTHROPATHY
L40.54

OTHER PSORIATIC ARTHROPATHY
L40.59

STEVENS-JOHNSON SYNDROME
L51.1

OTHER ERYTHEMA MULTIFORME
L51.8

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF UNSPECIFIED SITE
M05.40

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF RIGHT SHOULDER
M05.411

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF LEFT SHOULDER
M05.412

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF UNSPECIFIED SHOULDER
M05.419

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF RIGHT ELBOW
M05.421

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF LEFT ELBOW
M05.422

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF UNSPECIFIED ELBOW
M05.429

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF RIGHT WRIST
M05.431

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF LEFT WRIST
M05.432

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF UNSPECIFIED WRIST
M05.439

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF RIGHT HAND
M05.441

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF LEFT HAND
M05.442

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF UNSPECIFIED HAND
M05.449

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF RIGHT HIP
M05.451

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF LEFT HIP
M05.452

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF UNSPECIFIED HIP
M05.459

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF RIGHT KNEE
M05.461

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF LEFT KNEE
M05.462

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF UNSPECIFIED KNEE
M05.469

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF RIGHT ANKLE AND FOOT
M05.471

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF LEFT ANKLE AND FOOT
M05.472

RHEUMATOID MYOPATHY WITH RHEUMATOID ARTHRITIS OF UNSPECIFIED ANKLE AND FOOT
M05.479

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED SITE WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.70

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT SHOULDER WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.711

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT SHOULDER WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.712

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED SHOULDER WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.719

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT ELBOW WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.721

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT ELBOW WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.722

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED ELBOW WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.729

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT WRIST WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.731

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT WRIST WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.732

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED WRIST WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.739

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT HAND WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.741

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT HAND WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.742

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED HAND WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.749

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT HIP WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.751

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT HIP WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.752

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED HIP WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.759

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT KNEE WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.761

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT KNEE WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.762

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED KNEE WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.769

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT ANKLE AND FOOT WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.771

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT ANKLE AND FOOT WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.772

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED ANKLE AND FOOT WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.779

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF MULTIPLE SITES WITHOUT ORGAN OR SYSTEMS INVOLVEMENT
M05.79

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED SITE
M05.80

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT SHOULDER
M05.811

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT SHOULDER
M05.812

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED SHOULDER
M05.819

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT ELBOW
M05.821

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT ELBOW
M05.822

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED ELBOW
M05.829

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT WRIST
M05.831

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT WRIST
M05.832

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED WRIST
M05.839

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT HAND
M05.841

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT HAND
M05.842

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED HAND
M05.849

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT HIP
M05.851

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT HIP
M05.852

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED HIP
M05.859

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT KNEE
M05.861

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT KNEE
M05.862

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED KNEE
M05.869

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF RIGHT ANKLE AND FOOT
M05.871

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF LEFT ANKLE AND FOOT
M05.872

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF UNSPECIFIED ANKLE AND FOOT
M05.879

OTHER RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR OF MULTIPLE SITES
M05.89

RHEUMATOID ARTHRITIS WITH RHEUMATOID FACTOR, UNSPECIFIED
M05.9

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, UNSPECIFIED SITE
M06.00

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, RIGHT SHOULDER
M06.011

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, LEFT SHOULDER
M06.012

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, UNSPECIFIED SHOULDER
M06.019

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, RIGHT ELBOW
M06.021

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, LEFT ELBOW
M06.022

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, UNSPECIFIED ELBOW
M06.029

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, RIGHT WRIST
M06.031

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, LEFT WRIST
M06.032

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, UNSPECIFIED WRIST
M06.039

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, RIGHT HAND
M06.041

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, LEFT HAND
M06.042

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, UNSPECIFIED HAND
M06.049

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, RIGHT HIP
M06.051

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, LEFT HIP
M06.052

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, UNSPECIFIED HIP
M06.059

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, RIGHT KNEE
M06.061

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, LEFT KNEE
M06.062

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, UNSPECIFIED KNEE
M06.069

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, RIGHT ANKLE AND FOOT
M06.071

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, LEFT ANKLE AND FOOT
M06.072

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, UNSPECIFIED ANKLE AND FOOT
M06.079

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, VERTEBRAE
M06.08

RHEUMATOID ARTHRITIS WITHOUT RHEUMATOID FACTOR, MULTIPLE SITES
M06.09

OTHER SPECIFIED RHEUMATOID ARTHRITIS, UNSPECIFIED SITE
M06.80

OTHER SPECIFIED RHEUMATOID ARTHRITIS RIGHT SHOULDER
M06.811

OTHER SPECIFIED RHEUMATOID ARTHRITIS, LEFT SHOULDER
M06.812

OTHER SPECIFIED RHEUMATOID ARTHRITIS, UNSPECIFIED SHOULDER
M06.819

OTHER SPECIFIED RHEUMATOID ARTHRITIS, RIGHT ELBOW
M06.821

OTHER SPECIFIED RHEUMATOID ARTHRITIS, LEFT ELBOW
M06.822

OTHER SPECIFIED RHEUMATOID ARTHRITIS, UNSPECIFIED ELBOW
M06.829

OTHER SPECIFIED RHEUMATOID ARTHRITIS, RIGHT WRIST
M06.831

OTHER SPECIFIED RHEUMATOID ARTHRITIS, LEFT WRIST
M06.832

OTHER SPECIFIED RHEUMATOID ARTHRITIS, UNSPECIFIED WRIST
M06.839

OTHER SPECIFIED RHEUMATOID ARTHRITIS, RIGHT HAND
M06.841

OTHER SPECIFIED RHEUMATOID ARTHRITIS, LEFT HAND
M06.842

OTHER SPECIFIED RHEUMATOID ARTHRITIS, UNSPECIFIED HAND
M06.849

OTHER SPECIFIED RHEUMATOID ARTHRITIS, RIGHT HIP
M06.851

OTHER SPECIFIED RHEUMATOID ARTHRITIS, LEFT HIP
M06.852

OTHER SPECIFIED RHEUMATOID ARTHRITIS, UNSPECIFIED HIP
M06.859

OTHER SPECIFIED RHEUMATOID ARTHRITIS, RIGHT KNEE
M06.861

OTHER SPECIFIED RHEUMATOID ARTHRITIS, LEFT KNEE
M06.862

OTHER SPECIFIED RHEUMATOID ARTHRITIS, UNSPECIFIED KNEE
M06.869

OTHER SPECIFIED RHEUMATOID ARTHRITIS, RIGHT ANKLE AND FOOT
M06.871

OTHER SPECIFIED RHEUMATOID ARTHRITIS, LEFT ANKLE AND FOOT
M06.872

OTHER SPECIFIED RHEUMATOID ARTHRITIS, UNSPECIFIED ANKLE AND FOOT
M06.879

OTHER SPECIFIED RHEUMATOID ARTHRITIS, VERTEBRAE
M06.88

OTHER SPECIFIED RHEUMATOID ARTHRITIS, MULTIPLE SITES
M06.89

RHEUMATOID ARTHRITIS, UNSPECIFIED
M06.9

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS OF UNSPECIFIED SITE
M08.00

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, RIGHT SHOULDER
M08.011

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, LEFT SHOULDER
M08.012

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, RIGHT ELBOW
M08.021

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, LEFT ELBOW
M08.022

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED ELBOW
M08.029

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, RIGHT WRIST
M08.031

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, LEFT WRIST
M08.032

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED WRIST
M08.039

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, RIGHT HAND
M08.041

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, LEFT HAND
M08.042

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED HAND
M08.049

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, RIGHT HIP
M08.051

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, LEFT HIP
M08.052

RESOURCE PAGE. DO NOT NEED TO FAX BACK.

RHEUMATOLOGY, ***continued***

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED HIP
M08.059

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, RIGHT KNEE
M08.061

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, LEFT KNEE
M08.062

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED KNEE
M08.069

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, RIGHT ANKLE AND FOOT
M08.071

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, LEFT ANKLE AND FOOT
M08.072

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED ANKLE AND FOOT
M08.079

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, VERTEBRAE
M08.08

UNSPECIFIED JUVENILE RHEUMATOID ARTHRITIS, MULTIPLE SITES
M08.09

JUVENILE ANKYLOSING SPONDYLITIS
M08.1

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, UNSPECIFIED SITE
M08.20

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, RIGHT SHOULDER
M08.211

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, LEFT SHOULDER
M08.212

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, UNSPECIFIED SHOULDER
M08.219

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, RIGHT ELBOW
M08.221

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, LEFT ELBOW
M08.222

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, UNSPECIFIED ELBOW
M08.229

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, RIGHT WRIST
M08.231

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, LEFT WRIST
M08.232

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, UNSPECIFIED WRIST
M08.239

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, RIGHT HAND
M08.241

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, LEFT HAND
M08.242

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, UNSPECIFIED HAND
M08.249

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, RIGHT HIP
M08.251

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, LEFT HIP
M08.252

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, UNSPECIFIED HIP
M08.259

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, RIGHT KNEE
M08.261

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, LEFT KNEE
M08.262

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, UNSPECIFIED KNEE
M08.269

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, RIGHT ANKLE AND FOOT
M08.271

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, LEFT ANKLE AND FOOT
M08.272

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, UNSPECIFIED ANKLE AND FOOT
M08.279

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, VERTEBRAE
M08.28

JUVENILE RHEUMATOID ARTHRITIS WITH SYSTEMIC ONSET, MULTIPLE SITES
M08.29

JUVENILE RHEUMATOID POLYARTHRITIS (SERONEGATIVE)
M08.3

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED SITE
M08.40

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, RIGHT SHOULDER
M08.411

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, LEFT SHOULDER
M08.412

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED SHOULDER
M08.419

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, RIGHT ELBOW
M08.421

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, LEFT ELBOW
M08.422

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED ELBOW
M08.429

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, RIGHT WRIST
M08.431

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, LEFT WRIST
M08.432

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED WRIST
M08.439

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, RIGHT HAND
M08.441

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, LEFT HAND
M08.442

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED HAND
M08.449

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, RIGHT HIP
M08.451

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, LEFT HIP
M08.452

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED HIP
M08.459

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, RIGHT KNEE
M08.461

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, LEFT KNEE
M08.462

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED KNEE
M08.469

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, RIGHT ANKLE AND FOOT
M08.471

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, LEFT ANKLE AND FOOT
M08.472

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, UNSPECIFIED ANKLE AND FOOT
M08.479

PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS, VERTEBRAE
M08.48

SYSTEMIC LUPUS ERYTHEMATOSUS, ORGAN OR SYSTEM INVOLVED UNSPECIFIED
M32.10

ENDOCARDITIS IN SYSTEMIC LUPUS ERYTHEMATOSUS
M32.11

PERICARDITIS IN SYSTEMIC LUPUS ERYTHEMATOSUS
M32.12

LUNG INVOLVEMENT IN SYSTEMIC LUPUS ERYTHEMATOSUS
M32.13

GLOMERULAR DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS
M32.14

TUBULO-INTERSTITIAL NEUROPATHY IN SYSTEMIC LUPUS ERYTHEMATOSUS
M32.15

OTHER ORGAN OR SYSTEM INVOLVED IN SYSTEMIC LUPUS ERYTHEMATOSUS
M32.19

OTHER FORMS OF SYSTEMIC LUPUS ERYTHEMATOSUS
M32.8

SYSTEMIC LUPUS ERYTHEMATOSUS, UNSPECIFIED
M32.9

JUVENILE DERMATOPOLYMYOSITIS, ORGAN INVOLVEMENT UNSPECIFIED
M33.00

JUVENILE DERMATOPOLYMYOSITIS WITH RESPIRATORY INVOLVEMENT
M33.01

JUVENILE DERMATOPOLYMYOSITIS WITH MYOPATHY
M33.02

JUVENILE DERMATOPOLYMYOSITIS WITH OTHER ORGAN INVOLVEMENT
M33.09

OTHER DERMATOPOLYMYOSITIS, ORGAN INVOLVEMENT UNSPECIFIED
M33.10

OTHER DERMATOPOLYMYOSITIS WITH RESPIRATORY INVOLVEMENT
M33.11

OTHER DERMATOPOLYMYOSITIS WITH MYOPATHY
M33.12

OTHER DERMATOPOLYMYOSITIS WITH OTHER ORGAN INVOLVEMENT
M33.19

POLYMYOSITIS, ORGAN INVOLVEMENT UNSPECIFIED
M33.20

POLYMYOSITIS WITH RESPIRATORY INVOLVEMENT
M33.21

POLYMYOSITIS WITH MYOPATHY
M33.22

POLYMYOSITIS WITH OTHER ORGAN INVOLVEMENT
M33.29

DERMATOPOLYMYOSITIS, UNSPECIFIED, ORGAN INVOLVEMENT UNSPECIFIED
M33.90

DERMATOPOLYMYOSITIS, UNSPECIFIED WITH RESPIRATORY INVOLVEMENT
M33.91

DERMATOPOLYMYOSITIS, UNSPECIFIED WITH MYOPATHY
M33.92

DERMATOPOLYMYOSITIS, UNSPECIFIED WITH OTHER ORGAN INVOLVEMENT
M33.99

DERMATO(POLY)MYOSITIS IN NEOPLASTIC DISEASE
M36.0

ANKYLOSING SPONDYLITIS OF MULTIPLE SITES IN SPINE
M45.0

ANKYLOSING SPONDYLITIS OF OCCIPITO-ATLANTO-AXIAL REGION
M45.1

ANKYLOSING SPONDYLITIS OF CERVICAL REGION
M45.2

ANKYLOSING SPONDYLITIS OF CERVICOTHORACIC REGION
M45.3

ANKYLOSING SPONDYLITIS OF THORACIC REGION
M45.4

ANKYLOSING SPONDYLITIS OF THORACOLUMBAR REGION
M45.5

ANKYLOSING SPONDYLITIS OF LUMBAR REGION
M45.6

ANKYLOSING SPONDYLITIS OF LUMBOSACRAL REGION
M45.7

ANKYLOSING SPONDYLITIS SACRAL AND SACROCOCCYGEAL REGION
M45.8

ANKYLOSING SPONDYLITIS OF UNSPECIFIED SITES IN SPINE
M45.9

OTHER SERUM REACTION DUE TO OTHER SERUM, INITIAL ENCOUNTER
T80.69XA

OPHTHALMOLOGY

SARCOID IRIDOCYCLITIS
D86.83

DISCOID LUPUS ERYTHEMATOSUS OF RIGHT UPPER EYELID
H01.121

DISCOID LUPUS ERYTHEMATOSUS OF RIGHT LOWER EYELID
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H.P. Acthar GEL

(repository corticotropin injection) 80 U/mL

Acthar Hub
TEL: 1-888-435-2284
FAX: 1-877-937-2284

INDICATIONS AND USAGE

- **Infantile spasms:** H.P. Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- **Multiple Sclerosis:** H.P. Acthar Gel is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- **Rheumatic Disorders:** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis; Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis
- **Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- **Dermatologic Diseases:** Severe erythema multiforme, Stevens-Johnson syndrome
- **Allergic States:** Serum sickness
- **Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis; iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis; anterior segment inflammation
- **Respiratory Diseases:** Symptomatic sarcoidosis
- **Edematous State:** To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

IMPORTANT SAFETY INFORMATION

Contraindications

- Acthar should never be administered intravenously
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of Acthar
- Acthar is contraindicated where congenital infections are suspected in infants
- Acthar is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origins

Warnings and Precautions

- The adverse effects of Acthar are related primarily to its steroidogenic effects
- Acthar may increase susceptibility to new infection or reactivation of latent infections
- Suppression of the hypothalamic-pituitary-axis (HPA) may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by tapering of the dose when discontinuing treatment. During recovery of the adrenal gland patients should be protected from the stress (e.g. trauma or surgery) by the use of corticosteroids. Monitor patients for effects of HPA suppression after stopping treatment
- Cushing's syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Blood pressure, sodium and potassium levels may need to be monitored
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy
- Acthar can cause GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Monitor for signs of bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression, and psychosis. Existing conditions may be aggravated
- Patients with comorbid disease may have that disease worsened. Caution should be used when prescribing Acthar in patients with diabetes and myasthenia gravis
- Prolonged use of Acthar may produce cataracts, glaucoma and secondary ocular infections. Monitor for signs and symptoms
- Acthar is immunogenic and prolonged administration of Acthar may increase the risk of hypersensitivity reactions. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH activity
- There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients
- Decrease in bone density may occur. Bone density should be monitored for patients on long-term therapy
- Pregnancy Class C: Acthar has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

Adverse Reactions

- Common adverse reactions for Acthar are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain
- Specific adverse reactions reported in IS clinical trials in infants and children under 2 years of age included: infection, hypertension, irritability, Cushingoid symptoms, constipation, diarrhea, vomiting, pyrexia, weight gain, increased appetite, decreased appetite, nasal congestion, acne, rash, and cardiac hypertrophy. Convulsions were also reported, but these may actually be occurring because some IS patients progress to other forms of seizures and IS sometimes mask other seizures, which become visible once the clinical spasms from IS resolve

Other adverse events reported are included in the full Prescribing Information.

Please see accompanying full Prescribing Information and Medication Guide.

Mallinckrodt Pharmaceuticals

EXHIBIT B

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022432Orig1s000

OTHER REVIEW(S)

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications

Memorandum

****PRE-DECISIONAL AGENCY MEMO****

Date: **September 27, 2010**

To: Susan Daugherty
Senior Regulatory Health Project Manager
DNP

CC: Mary Dempsey
Project Management Officer
OSE, DRISK

Sharon Mills
Acting Team Leader
OSE, DRISK

From: Sharon Watson, PharmD
Regulatory Review Officer
Division of Drug Marketing, Advertising, and Communications (DDMAC)

Subject: Drug: H.P. Acthar® Gel (Repository Corticotropin)
NDA: 022432

DDMAC has reviewed the 9/24/10 DRISK review of the proposed Medication Guide (Med Guide) for H.P. Acthar Gel in comparison with the proposed FDA-approved product labeling (PI). DDMAC's comments are provided directly on the clean version of this proposed Med Guide document, attached below.

Thank you for the opportunity to comment on this proposed Med Guide.

If you have any questions or concerns regarding these comments, please contact me.

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/s/

SHARON M WATSON
09/27/2010

Division of Drug Marketing, Advertisement, and Communications

Internal Consult

****Pre-decisional Agency Information****

To: Russell Katz, MD, Director, Division of Neurology Products (DNP)
Norman Hershkowitz, MD, Team Leader, DNP
Susan B Daugherty, Senior Regulatory Project Manager, DNP

From: Quynh-Van Tran, PharmD, BCPP
Regulatory Reviewer, Division of Drug Marketing, Advertising, and Communications, (DDMAC)

CC: Andy Haffer, PharmD, Group Leader, DDMAC

Date: September 24, 2010

Re: Comments on draft labeling (Package Insert) for H.P. Acthar Gel (repository corticotropin) Injection

NDA 22-432

Thank you for the opportunity to review the proposed PI for H.P. Acthar Gel (FDA dated version 9/20/2010). Please see attached PI with our comments incorporated therein.

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/s/

QUYNH-VAN TRAN
09/27/2010

CLINICAL CONSULTATION

DATE CONSULT RECEIVED: Jan. 19, 2010

DATE CONSULT COMPLETED: May 26, 2010

FROM: William Lubas, MD-PhD, Medical Officer
Division of Metabolism and Endocrinology Products, HFD-510

THROUGH: Dragos Roman, MD, Team Leader, DMEP
Mary Parks, MD, Division Director, DMEP

TO: Susan Daugherty, RPM
Division of Neurology Products

SUBJECT: PLR review of H.P. Acthar Gel

MATERIAL EVALUATED IN THIS REVIEW

- The consult request from Division of Neurology Products
- Latest PLR version of submitted to the EDR on April 28, 2010
  \\FDSWA150\NONECTD\N22432\N_000\2010-04-28
- H.P. Acthar Gel and Cosyntropin Review: Clinical and Financial Implications.
  http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2697107/pdf/ptj34_5p250.pdf
- PLR version of Flo-Pred (prednisolone acetate) steroid class label
  http://darrts/darrts/ViewDocument?documentId=090140af801d4109

INTRODUCTION

H. P. Acthar Gel (Repository Corticotropin Injection) contains the full length 39-amino acid human native ACTH molecule in a 16% gelatin gel to provide for prolonged release after intramuscular or subcutaneous injection. Endogenous ACTH stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. It is presumed that the mechanism of action of H. P. Acthar Gel is most likely mediated by the relative increase in production of these individual steroid hormones, however, the exact mechanism of action for specific indications, such as treatment of infantile spasms, is not known.

Repository Corticotropin Injection was originally approved in 1952 for a variety of disorders and diseases that at the time were thought to benefit from steroid mediated immunosuppression including:

> COLLAGEN DISEASES - Acute Lupus Erythematosus; Psoriatic Arthritis; Rheumatoid Arthritis; Rheumatic Fever; Rheumatoid Spondylitis; Still's Disease.

HYPERSENSITIVITIES – Acquired Hemolytic Jaundice, Angioneurotic Edema, Contact Dermatitis, Drug Sensitivities, Severe Bronchial Asthma, Severe Hay Fever, Urticaria.

ACUTE INLFAMMATORY DISEASES OF THE EYE - Acute Secondary Glaucoma; Choroiditis; Conjunctivitis; Iritis; Keratitis; Optic Neuritis; Sympathetic Ophthalmia; Uveitis.

ACUTE INLFAMMATORY DISEASES OF THE SKIN – Acute Psoriasis unresponsive to usual treatment, Exfoliative Dermatitis, Severe Pemphigus.

NEPHROTIC SYNDROME

METABOLIC DISEASES – Acute Gouty Arthritis, Congenital Idiopathic Hypoglycemia.

ULCERATIVE COLITIS

ALCHOLISM AND DELIRIUM TREMENS

BURNS

BURSISTIS; TENOSYNOVITIS

PANHYPOPITUITARISM

OTHER USES – ACTHAR (Corticotropin) preparation have also been used in numerous other disease states, such as: Diagnosing adrenal cortical insufficiency and Addison's disease, Acute Leukemia and Chronic Lymphatic Leukemia; Acute Overwhelming Infections; Agranulocytosis; Beryllium Poisoning; Guillain-Barre Syndrome; Hodgkin's Disease; Loeffler's Syndrome; Stevens-Johnson Syndrome; Radiation Sickness, and Vasomotor Rhinitis.

The initial approval of H.P. ACTH gel occurred prior to the Kefauver-Harris amendment to the Federal Food, Drug and Cosmetic Act of 1962, which introduced the requirement of "substantial evidence" of two adequate and well controlled trials. At the time of the original approval drug manufacturers only had to show the drug was safe for use in humans. The original data included case reports from a few physicians describing patients with conditions originally treated with Acthar powder that were transferred to treatment with Acthar Gel and gave dosing guidance for treatment of these individual conditions. A few patients had improvements in hematology data and improvement in symptoms (decreased diarrhea, improved appetite, sense of well being, etc.) reported to support the efficacy of treatment. Additional indications for sarcoidosis, anogenital pruritis, nonsuppurative thyroiditis, and nontropical sprue were added in 1954 using additional information from case reports in the literature. These data would be grossly

inadequate to support approval of a new drug or new indications by the Agency under current standards requiring evidence from adequate and well-controlled clinical trials.

A Drug Efficacy Study Implementation (DESI) review of corticotrophin injection was initiated in 1971 and finalized in 1977. Changes to the package insert as part of the initiation of the DESI review in 1971 included the following:

> H.P. ACTHAR® GEL (Repository Corticotropin Injection) is indicated for diagnostic testing of adrenocortical function.
>
> H.P. ACTHAR GEL® (Repository Corticotropin Injection) has limited therapeutic value in those conditions responsive to corticosteroid therapy; however, corticosteroid therapy is considered to be the treatment of choice. H.P. ACTHAR® GEL (Repository Corticotropin Injection) may be employed in the following disorders:
>
> > RHEUMATIC DISORDERS: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis; Ankylosing spondylitis; Acute and subacute bursitis; Acute nonspecific tenosynovitis; Acute gouty arthritis.
> >
> > COLLAGEN DISEASES: During an exacerbation or as maintenance in selected cases of Systemic lupus erythematosus; Systemic Dermatomyositis (polymyositis); Acute Rheumatic carditis.
> >
> > DERMATOLOGIC DISEASES: Pemphigus; Bullous dermatitis herpetiformis; Severe erythema multiforme (Stevens- Johnson syndrome); Exfoliative dermatitis; Severe psoriasis.
> >
> > ALLERGIC STATES: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment—Seasonal or perennial allergic rhinitis; Bronchial asthma; Contact dermatitis; Atopic dermatitis; Serum sickness.
> >
> > OPHTHALMIC DISEASES: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: Allergic conjunctivitis; Keratitis; Herpes zoster ophthalmicus Iritis; Diffuse posterior uveitis and choroiditis; Optic neuritis; Sympathetic ophthalmia.
> >
> > RESPIRATORY DISEASES: Symptomatic sarcoidosis; Loeffler's syndrome not manageable by other means; Berylliosis.
> >
> > HEMATOLOGIC DISORDERS: Acquired (autoimmune) hemolytic anemia.
> >
> > NEOPLASTIC DISEASES: For palliative management of: Leukemias and lymphomas in adults; Acute leukemia of childhood.

EDEMATOUS STATE: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

MISCELLANEOUS: Tuberculous meningitis with subarachnoid block or impending block when concurrently accompanied by appropriate antituberculous chemotherapy. Trichinosis of neurologic or myocardial involvement.

ACTHAR® (Corticotropin Injection) and H.P ACTHAR® GEL (Repository Corticotropin Injection) may also be useful in the following conditions:

METABOLIC DISORDER: Congenital idiopathic hypoglycemia.

ALLERGIC STATES: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment: Angioedema; Urticaria.

RESPIRATORY DISEASES: Pulmonary emphysema where bronchospasm or bronchial edema plays a significant role.

GASTROINTESTINAL DISEASES: To tide the patient over a critical period of the disease in: Ulcerative colitis; Crohn's disease; Intractable sprue.

HEMATOLOGIC DISORDERS: Infectious mononucleosis

The following additional indications were added in 1977 as part of S-016:

ENDOCRINE DISORDERS: Nonsupportive thyroiditis; Hypercalcemia associated with cancer.

RHEUMATIC DISORDERS: Post-traumatic arthritis; Synovitis of osteoarthritis; Epicondylitis.

DERMATOLOGIC DISEASES: Severe seborrheic dermatitis; Mycosis fungoides.

OPHTHALMIC DISEASES section: Iridocyclitis; Chorioretinitis; Anterior segment inflammation; Allergic corneal marginal ulcers.

RESPIRATORY DISEASES section: Fulminating or disseminated pulmonary tuberculosis when used concurrently with antituberculous chemotherapy; Aspiration pneumonitis.

HEMATOLOGIC DISORDERS section: Idiopathic thrombocytopenia purpura in adults (i.v. only; I.M. is contraindicated); Secondary thrombocytopenia in adults; Erythroblastopenia (RBC anemia); Congenital (erythroid) hypoplastic anemia.

GASTROINTESTINAL DISEASES section: Regional enteritis.

MISCELLANEOUS section: Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy. Trichinosis of neurologic or myocardial involvement.

An additional indication for the treatment of acute exacerbations of multiple sclerosis was added in 1979, S-018.

The indication for use in ITP was removed as part of S-024 in 1981.

(b) (4)

Supplement SLR-039 in June of 2006 again sought to add the indication for the treatment of infantile spasms. This time the sponsor submitted a literature review and a meta analysis of eight randomized controlled trials. A May 2007 review by Drs. Schrager, Kehoe and Parks in DMEP again concluded that (b) (4) (b) (4) H.P. Acthar gel and a Not Approvable letter was issued. It was recommended that the sponsor address these deficiencies with a resubmission to the Division of NeuroPharmacology Products.

A complete response to NDA 08-372, SLR-039 was submitted under NDA 22-432 in March 2009. This includes a reanalysis of the most relevant publication (Baram 1996) and a retrospective chart review to support their currently proposed dosing scheme for infantile spasms.

No specific questions were included as part of this consult request. DMEP was instead asked to review the latest PLR version of the label for clarity and correctness.

REVIEW

Diagnostic Testing of Adrenocortical Function

The current package insert recommends the use of H.P. Acthar Gel for diagnostic testing of adrenocortical function; however, there is no reference to support the proposed indication. The dosing recommendation suggests that doses of as much as 80 units as a

single injection, or more injections of a lesser dose, may be used but that dosage and frequency should be individualized without giving any recommendations on how that should be done. It also gives no information on how to interpret the test results.

A review of the PubMed literature by this medical reviewer failed to identify any current references that refer to the use of the ACTH Acthar Gel for adrenocortical function testing. A 1995 version of de Groot and Jameson did mention the use of an alternative 48hr ACTH Infusion Test, but concluded that "the test requires hospitalization to perform and mainly for that reason has become obsolete in the differential diagnosis of adrenal insufficiency." In addition, Acthar Gel is contraindicated for IV infusion and the ACTH Infusion Test would have required the use of Acthar Powder which is no longer marketed. Other current references such as: De Groot, William's, Harrison's, the Merck Manual and ACP PIER & AHFS DI, instead recommend the currently approved cosyntropin test for adrenocortical function testing. This test has the advantage that in most cases the result can be obtained 30 minutes after the IV injection. Even the diagnosis of secondary adrenal insufficiency which might benefit from a longer testing period is recommended to be performed by standard short-term cosyntropin testing after several days of short term priming of the adrenal. Therefore, it is this medical reviewer's conclusion that the current evidence to support the dose and testing of adrenocortical function with Acthar Gel is inadequate and that this indication should be removed during the PLR conversion. If the sponsor wishes to maintain this indication, they should submit data to support a validated testing procedure. These data must include information on how to determine the appropriate testing dose and how to interpret the study results to conclude a diagnosis of adrenal insufficiency.

Endocrine Disorders

The current package insert includes two endocrine disorders with indications for treatment with H.P. Acthar Gel: nonsuppurative thyroiditis and hypercalcemia associated with cancer. Neither of these is a common indication for the use of Acthar Gel in current clinical practice. Painful subacute thyroiditis is usually treated with NSAIDs and if that fails prednisone is an alternative. Hypercalcemia associated with cancer is treated with intravenous hydration, diuretics, bisphosphonates, and gallium nitrate. Steroids can be useful in cases of multiple myeloma and lymphoma but as previously discussed there is no benefit to the use of H.P. Acthar therapy over standard steroid treatment. The original approval of H.P. Acthar Gel did not include these specific indications, nonsuppurative thyroiditis and hypercalcemia associated with cancer, and they were added in a later supplement using case reports from that literature as the supportive evidence.

A search in PubMed by this medical reviewer for references supporting the use of ACTH/corticotrophin for these endocrine indications was unsuccessful. For example: A search using the keywords. "ACTH" and "nonsuppurative thyroiditis" retrieved three references: two foreign and one in English (from Nov. 1953) but none had abstracts available on line for review. A search for the keywords "ACTH" and "hypercalcemia" and "cancer" identified 84 references, none of which referred to ACTH as a potential treatment for hypercalcemia associated with cancer. As there is inadequate evidence to support the safe and effective use of H. P. Acthar Gel for these specific endocrine

indications, DMEP would recommend removal of these indications from the package insert during the PLR conversion.

Use in Children over 2 years of Age and Adults for Indications Other than Infantile Spasms and Multiple Sclerosis

The question arises whether there is sufficient evidence to support the other potential indications in the following categories: nervous system, rheumatic, collagen, dermatologic, allergic states, ophthalmic, respiratory, hematologic, neoplastic, edematous, gastrointestinal, and miscellaneous, which are currently part of the H.P. Acthar Gel package insert. A search of Pubmed using the keyword "acthar" identified only 11 references of which only three reports dealt specifically with possible treatment indications: infantile spasms[1], hay fever[2] and sarcoidosis[3]. A recent review of the clinical utility of H.P. Acthar Gel, by Gettig et al.[4], which included an extensive search of the literature, confirmed that there are currently only three potential common uses for this medication despite the extensive list of potential uses included in the package insert. They include adrenocortical function testing, treatment of infantile spasms and treatment of multiple sclerosis. As the PLR conversion of the package insert offers an opportunity to reassess the quality of the evidence used to support the current indications it seems reasonable to recommend removal of these unsupported indications. The sponsor should be encouraged to submit evidence of adequate and well controlled trials to support any of these indications that they wish to retain. Consideration of the evidence in support of these other indications should be directed to the appropriate review division which has expertise in the particular medical condition (e.g., severe seborrheic dermatitis should be reviewed by the Division of Dermatalogy and Dental Products).

Use in Adults for Multiple Sclerosis

The current package insert recommends daily intramuscular injections of 80 -120 Units for 2-3 weeks for the treatment of acute exacerbations of multiple sclerosis. It is recommended that the Division of NeuroPharmacology review the PLR conversion for this indication.

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[1] Discharge planning for the child with infantile spasms. Kongelbeck SR. J Neurosci Nurs. 1990 Aug;22(4):238-44.

[2] Comparison of a low and high dose ACTH gel in the treatment of hay fever. Parr EJ, Davies BH. Clin Allergy. 1980 Mar;10(2):195-202.

[3] Effect of Acthar-c (ACTH) in sarcoidosis. MILLER MA, BASS HE. Ann Intern Med. 1952 Oct ; 37(4):776-84

[4] H.P. Acthar Gel and Cosyntropin Review: Clinical and Financial Implications. Gettig J, Cummings JP, Matuszewski K. P T. 2009 May;34(5):250-257.

LABELING RECOMMENDATIONS

Highlights Section
INDICATIONS AND USAGE

Delete the initial indication for [redacted] (b) (4)

Replace the second paragraph:

- [redacted] (b) (4)

with the following:

- H.P. Acthar Gel may be used for the treatment of acute exacerbations of multiple sclerosis.

DOSAGE AND ADMINISTRATION
Delete the first two paragraphs describing [redacted] (b) (4).

WARNINGS AND PRECAUTIONS
Revise to more closely resemble recent PLR class labeling for steroids.

USE IN SPECIFIC POPULATIONS
Delete the section on nursing mothers.

1 INDICATIONS AND USAGE

Delete the second paragraph describing [redacted] (b) (4).

Replace the third paragraph:

[redacted] (b) (4)

with the following:

Use in Adults: H.P. Acthar Gel (repository corticotropin injection) is indicated for the treatment of exacerbations of multiple sclerosis.

Delete sections 1.1 to 1.15

2 DOSAGE AND ADMINISTRATION
Section 2.1- delete all but the last paragraph describing use in the treatment of exacerbations of multiple sclerosis, and revise according to Neuropharmacology recommendations.

Section 2.2- recommend revision by Neuropharmacology which is reviewing the infantile spasms indication.

5 WARNINGS AND PRECAUTIONS
Recommend revising this section to more closely resemble steroids class labeling (see recent PLR conversion for Flo-Pred). For example there is currently no mention of GI perforation, negative effects on bone density, negative effects on growth and development in pediatric patients, behavioral or mood disturbances, hypothalamic-pituitary-adrenal axis suppression, risk for fetal harm, Cushing's syndrome and hyperglycemia in the current WARNINGS AND PRECAUTIONS section.

8 USE IN SPECIFIC POPULATIONS
Renumber sections: Nursing Mother to 8.3 and Pediatric Use to 8.4 as per labeling guidance.

14 CLINICAL STUDIES
Recommend that Neuropharmacology revise this section to support the two revised indications: infantile spasms and multiple sclerosis.

15 REFERENCES
Delete this section as per recent labeling guidance.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22432	ORIG-1	QUESTCOR PHARMACEUTICALS INC	H.P.ACTHAR GEL (Repository Corticotropin Injection)

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/s/

WILLIAM A LUBAS
05/28/2010

DRAGOS G ROMAN
05/28/2010

MARY H PARKS
05/28/2010

505(b)(2) ASSESSMENT

Application Information		
NDA # 022432	NDA Supplement #: S- n/a	Efficacy Supplement Type SE- 1
Proprietary Name: H.P. Acthar Gel Established/Proper Name: (repository corticotropin injection) Dosage Form: injection Strengths:		
Applicant: Questcor Pharmaceuticals		
Date of Receipt: June 23, 2006		
PDUFA Goal Date: June 11, 2010	Action Goal Date (if different):	
Proposed Indication(s): Infantile Spasms		

GENERAL INFORMATION

1) Is this application for a recombinant or biologically-derived product and/or protein or peptide product *OR* is the applicant relying on a recombinant or biologically-derived product and/or protein or peptide product to support approval of the proposed product?

H.P. Acthar Gel (repository corticotropin injection) is a highly purified sterile preparation of the adrenocorticotropic hormone, however, this product is regulated as a drug per 21 CFR 3.5.

YES ☒ NO ☐

*If "**YES** "contact the (b)(2) review staff in the Immediate Office, Office of New Drugs.*

INFORMATION PROVIDED VIA RELIANCE (LISTED DRUG OR LITERATURE)

2) List the information essential to the approval of the proposed drug that is provided by reliance on our previous finding of safety and efficacy for a listed drug or by reliance on published literature. *(If not clearly identified by the applicant, this information can usually be derived from annotated labeling.)*

Source of information* (e.g., published literature, name of referenced product)	Information provided (e.g., pharmacokinetic data, or specific sections of labeling)

*each source of information should be listed on separate rows

3) Reliance on information regarding another product (whether a previously approved product or from published literature) must be scientifically appropriate. An applicant needs to provide a scientific "bridge" to demonstrate the relationship of the referenced and proposed products. Describe how the applicant bridged the proposed product to the referenced product(s). (Example: BA/BE studies)

N/A

RELIANCE ON PUBLISHED LITERATURE

4) (a) Regardless of whether the applicant has explicitly stated a reliance on published literature to support their application, is reliance on published literature necessary to support the approval of the proposed drug product (i.e., the application *cannot* be approved without the published literature)?

YES ☐ NO ☒
*If "**NO**," proceed to question #5.*

(b) Does any of the published literature necessary to support approval identify a specific (e.g., brand name) *listed* drug product?

YES ☐ NO ☐
*If "**NO**", proceed to question #5.*
*If "**YES**", list the listed drug(s) identified by name and answer question #4©.*

(c) Are the drug product(s) listed in (b) identified by the applicant as the listed drug(s)?

YES ☐ NO ☐

RELIANCE ON LISTED DRUG(S)

Reliance on published literature which identifies a specific approved (listed) drug constitutes reliance on that listed drug. Please answer questions #5-9 accordingly.

5) Regardless of whether the applicant has explicitly referenced the listed drug(s), does the application **rely** on the finding of safety and effectiveness for one or more listed drugs (approved drugs) to support the approval of the proposed drug product (i.e., the application cannot be approved without this reliance)?

YES ☐ NO ☒

*If "**NO**," proceed to question #10.*

6) Name of listed drug(s) relied upon, and the NDA/ANDA #(s). Please indicate if the applicant explicitly identified the product as being relied upon (see note below):

Name of Drug	NDA/ANDA #	Did applicant specify reliance on the product? (Y/N)

Applicants should specify reliance on the 356h, in the cover letter, and/or with their patent certification/statement. If you believe there is reliance on a listed product that has not been explicitly identified as such by the applicant, please contact the (b)(2) review staff in the Immediate Office, Office of New Drugs.

7) If this is a (b)(2) supplement to an original (b)(2) application, does the supplement rely upon the same listed drug(s) as the original (b)(2) application?

N/A ☐ YES ☐ NO ☐

*If this application is a (b)(2) supplement to an original (b)(1) application or not a supplemental application, answer **"N/A"**.*

*If "**NO**", please contact the (b)(2) review staff in the Immediate Office, Office of New Drugs.*

8) Were any of the listed drug(s) relied upon for this application:

a) Approved in a 505(b)(2) application?

YES ☐ NO ☐

*If "**YES**", please list which drug(s).*

Name of drug(s) approved in a 505(b)(2) application:

b) Approved by the DESI process?

YES ☐ NO ☐

*If "**YES**", please list which drug(s).*

Name of drug(s) approved via the DESI process:

c) Described in a monograph?

YES ☐ NO ☐

*If "**YES**", please list which drug(s).*

Name of drug(s) described in a monograph:

d) Discontinued from marketing?

YES ☐ NO ☐

*If "**YES**", please list which drug(s) and answer question d) i. below.*
*If "**NO**", proceed to question #9.*

Name of drug(s) discontinued from marketing:

i) Were the products discontinued for reasons related to safety or effectiveness?

YES ☐ NO ☐

(Information regarding whether a drug has been discontinued from marketing for reasons of safety or effectiveness may be available in the Orange Book. Refer to section 1.11 for an explanation, and section 6.1 for the list of discontinued drugs. If a determination of the reason for discontinuation has not been published in the Federal Register (and noted in the Orange Book), you will need to research the archive file and/or consult with the review team. Do not rely solely on any statements made by the sponsor.)

9) Describe the change from the listed drug(s) relied upon to support this (b)(2) application (for example, "This application provides for a new indication, otitis media" or "This application provides for a change in dosage form, from capsule to solution").

The purpose of the following two questions is to determine if there is an approved drug product that is equivalent or very similar to the product proposed for approval that should be referenced as a listed drug in the pending application.

*The assessment of pharmaceutical equivalence for a recombinant or biologically-derived product and/or protein or peptide product is complex. If you answered **YES to question #1**, proceed to question #12; if you answered **NO to question #1**, proceed to question #10 below.*

10) (a) Is there a pharmaceutical equivalent(s) to the product proposed in the 505(b)(2) application that is already approved (via an NDA or ANDA)?

*(**Pharmaceutical equivalents** are drug products in identical dosage forms that: **(1)** contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; **(2)** do not necessarily contain the same inactive ingredients; **and** **(3)** meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates. (21 CFR 320.1(c)).*

***Note** that for proposed combinations of one or more previously approved drugs, a pharmaceutical equivalent must also be a combination of the same drugs.*

YES ☐ NO ☒

*If "**NO**" to (a) proceed to question #11.*
*If "**YES**" to (a), answer (b) and (c) then proceed to question #12.*

(b) Is the pharmaceutical equivalent approved for the same indication for which the 505(b)(2) application is seeking approval?

YES ☐ NO ☐

(c) Is the listed drug(s) referenced by the application a pharmaceutical equivalent?

YES ☐ NO ☐

*If "**YES**" to (c) and there are no additional pharmaceutical equivalents listed, proceed to question #12.*
*If "**NO**" or if there are additional pharmaceutical equivalents that are not referenced by the application, list the NDA pharmaceutical equivalent(s); you do not have to individually list all of the products approved as ANDAs, but please note below if approved approved generics are listed in the Orange Book. Please also contact the (b)(2) review staff in the Immediate Office, Office of New Drugs.*

Pharmaceutical equivalent(s):

11) (a) Is there a pharmaceutical alternative(s) already approved (via an NDA or ANDA)?

*(**Pharmaceutical alternatives** are drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form or as the same salt or ester. Each such drug product individually meets either the identical or its own respective compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times and/or dissolution rates. (21 CFR 320.1(d)) Different dosage forms and strengths within a product line by a single manufacturer are thus pharmaceutical alternatives, as are extended-release products when compared with immediate- or standard-release formulations of the same active ingredient.)*

***Note** that for proposed combinations of one or more previously approved drugs, a pharmaceutical alternative must also be a combination of the same drugs.*

YES ☐ NO ☒
*If "**NO**", proceed to question #12.*

(b) Is the pharmaceutical alternative approved for the same indication for which the 505(b)(2) application is seeking approval?

YES ☐ NO ☐

(c) Is the approved pharmaceutical alternative(s) referenced as the listed drug(s)?

YES ☐ NO ☐

*If "**YES**" and there are no additional pharmaceutical alternatives listed, proceed to question #12.*
*If "**NO**" or if there are additional pharmaceutical alternatives that are not referenced by the application, list the NDA pharmaceutical alternative(s); you do not have to individually list all of the products approved as ANDAs, but please note below if approved generics are listed in the Orange Book. Please also contact the (b)(2) review staff in the Immediate Office, Office of New Drugs.*

Pharmaceutical alternative(s):

PATENT CERTIFICATION/STATEMENTS

12) List the patent numbers of all unexpired patents listed in the Orange Book for the listed drug(s) for which our finding of safety and effectiveness is relied upon to support approval of the (b)(2) product.

Listed drug/Patent number(s):

No patents listed ☒ *proceed to question #14*

13) Did the applicant address (with an appropriate certification or statement) all of the unexpired patents listed in the Orange Book for the listed drug(s) relied upon to support approval of the (b)(2) product?

YES ☐ NO ☐

*If "**NO**", list which patents (and which listed drugs) were not addressed by the applicant.*

Listed drug/Patent number(s):

14) Which of the following patent certifications does the application contain? *(Check all that apply and identify the patents to which each type of certification was made, as appropriate.)*

☐ No patent certifications are required (e.g., because application is based solely on published literature that does not cite a specific innovator product)

☐ 21 CFR 314.50(i)(1)(i)(A)(1): The patent information has not been submitted to FDA. (Paragraph I certification)

☐ 21 CFR 314.50(i)(1)(i)(A)(2): The patent has expired. (Paragraph II certification)

Patent number(s):

☐ 21 CFR 314.50(i)(1)(i)(A)(3): The date on which the patent will expire. (Paragraph III certification)

Patent number(s): Expiry date(s):

☐ 21 CFR 314.50(i)(1)(i)(A)(4): The patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted. (Paragraph IV certification). *If Paragraph IV certification was submitted, proceed to question #15.*

☐ 21 CFR 314.50(i)(3): Statement that applicant has a licensing agreement with the NDA holder/patent owner (must also submit certification under 21 CFR 314.50(i)(1)(i)(A)(4) above). *If the applicant has a licensing agreement with the NDA holder/patent owner, proceed to question #15.*

☒ 21 CFR 314.50(i)(1)(ii): No relevant patents.

☐ 21 CFR 314.50(i)(1)(iii): The patent on the listed drug is a method of use patent and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent as described in the corresponding use code in the Orange Book. Applicant must provide a statement that the method of use patent does not claim any of the proposed indications. (Section viii statement)

Patent number(s):
Method(s) of Use/Code(s):

15) Complete the following checklist ***ONLY*** for applications containing Paragraph IV certification and/or applications in which the applicant and patent holder have a licensing agreement:

(a) Patent number(s):
(b) Did the applicant submit a signed certification stating that the NDA holder and patent owner(s) were notified that this b(2) application was filed [21 CFR 314.52(b)]?

YES ☐ NO ☐

*If "**NO**", please contact the applicant and request the signed certification.*

(c) Did the applicant submit documentation showing that the NDA holder and patent owner(s) received the notification [21 CFR 314.52(e)]? This is generally provided in the form of a registered mail receipt.

YES ☐ NO ☐

*If "**NO**", please contact the applicant and request the documentation.*

(d) What is/are the date(s) on the registered mail receipt(s) (i.e., the date(s) the NDA holder and patent owner(s) received notification):

Date(s):

(e) Has the applicant been sued for patent infringement within 45-days of receipt of the notification listed above?

***Note** that you may need to call the applicant (after 45 days of receipt of the notification) to verify this information **UNLESS** the applicant provided a written statement from the notified patent owner(s) that it consents to an immediate effective date of approval.*

YES ☐ NO ☐ Patent owner(s) consent(s) to an immediate effective date of approval ☐

EXHIBIT C

NEWSROOM

NEWS RELEASES

Mallinckrodt Statement on H.P. Acthar® Gel (Repository Corticotropin Injection) Update

UPDATED June 22, 2017

To address the false and misleading information about Mallinckrodt Pharmaceuticals and its product H.P. Acthar Gel, the company is committed to regularly providing important facts about this critical medicine.

H.P. Acthar Gel makes a significant difference in the lives of very sick patients with unmet medical needs. The U.S. Food and Drug Administration (FDA) reviewed H.P. Acthar Gel's label in 2010, and determined there was sufficient scientific and clinical evidence to support the 19 indications now in the current label. In most indications, H.P. Acthar Gel is a later line treatment, prescribed by skilled healthcare providers to a small subset of patients who need an alternative treatment option. H.P. Acthar Gel is a first line monotherapy treatment for infantile spasms (IS).

***UPDATE:* Adverse Event Reports**
Mallinckrodt annually provides the FDA with data about adverse events related to its marketed products. As we approach our yearly filing, we are pleased to report that the positive benefit-risk of H.P. Acthar Gel has remained unchanged across all marketed indications and is consistent with previous years.

To derive meaningful conclusions of this topic, adverse event reports for H.P. Acthar Gel need to be considered within the appropriate context.

H.P. Acthar Gel is typically prescribed to patients with very serious medical conditions, often as a third or fourth line of treatment when other treatments have failed. It is well known that many of these patients suffer from diseases in which co-morbidities are high, and often they are on other medications that may be contributing factors.

The frequency of adverse event reports also does not necessarily correlate to an increase in the actual prevalence or relative severity of any particular side effect or event. Each event is reported and counted whether it relates to a relatively minor event such as a headache or a more serious event such as anaphylaxis.

Furthermore, the FDA itself cautions on its website that reporting of a side effect or adverse event occurring while taking a drug doesn't establish a causal relationship between the adverse event and the medicine.

Over the past years, the number of patients using H.P. Acthar Gel has increased significantly. Critically, however, company-generated H.P. Acthar Gel data on adverse events over the last three calendar years indicates that the number of serious adverse events as a proportion of the number of H.P. Acthar Gel prescriptions (measured by vials sold) has remained very low and consistent with the FDA's independent analysis.

Body of Evidence
There is clinical evidence to support the effectiveness of H.P. Acthar Gel. For instance, two randomized clinical trials were conducted to support the effectiveness of the drug in obtaining FDA approval as a treatment for infantile spasms, one of which compared H.P. Acthar Gel to prednisone, where 86.7% of patients responded to H.P. Acthar Gel vs. 28.6% that responded to prednisone. The IS clinical trial results appear in Section 14 of the full prescribing information for the drug. A representative sampling of articles citing the clinical experience of the drug follow:

- Baughman, R, Barney, J, O'Hare, L, Lower, E. A retrospective pilot study examining the use of H.P. Acthar Gel in sarcoidosis patients. Respiratory Medicine 110 (2016) 66-72. Link.
- Berkovich R, Agius, M. Mechanisms of action of ACTH in the management of relapsing forms of multiple sclerosis. Ther Adv Neurol Disord. 2014;7(2):83-96. Link.
- Thompson AJ, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. Neurology. 1989;39:969-97. Link.
- Rose AS, Kuzma JW, Kurtzke JF, Namerow NS, Sibley WA, Tourtellotte WW. Cooperative study in the evaluation of therapy in multiple sclerosis. ACTH vs. placebo--final report. Neurology. 1970;20(5):1-59. Link.
- Hogan J, Bomback AS, Mehta K, et al. Treatment of idiopathic FSGS with adrenocorticotropic hormone gel. Clin J Am Soc Nephrol. 2013;8(12):2072-2081. Link.
- Bomback AS, Canetta PA, Beck LH, Ayalon R, Radhakrishnan J, Appel GB. Treatment of resistant glomerular diseases with adrenocorticotropic hormone gel: A prospective trial. American Journal of Nephrology. 2012;36(1):58-67. Link.

Significant additional evidence exists, including company-sponsored controlled clinical trials, investigator-initiated research conducted in top hospitals and medical centers by some of the country's preeminent physicians, and health economic and outcomes research data. A bibliography referencing hundreds of studies related to H.P. Acthar Gel can be found on the company's website, and press releases specific to company-sponsored trials for the product can also be found in the news section of the site. Equally important are the more than 50 years of clinical experience physicians have with the product as a demonstrated therapy for appropriate patients.

Mallinckrodt Investment

As the company has stated consistently, Mallinckrodt's goal has been - and continues to be – to acquire under-resourced, under-utilized products like H.P. Acthar Gel that are used in areas of high unmet medical need, typically in narrow patient populations, and then invest significantly in those products. The company invests by building an even larger body of evidence to demonstrate which patients can benefit most from the drug and shares that information with physicians and payers to ensure those patients can get access to the product. This strategy has been very successful, and in the roughly 2.5 years it has owned the product, Mallinckrodt has expanded the number of commercial lives under contract from zero to nearly 60%.

Since acquiring H.P. Acthar Gel in 2014, Mallinckrodt has invested more than a quarter of a billion dollars into the drug, including building a larger body of evidence for the drug through clinical trials and health economic outcomes research data; payer engagement; manufacturing modernization; and other medical affairs and research activities. Since adding the drug to its portfolio, Mallinckrodt has initiated six well-designed, company-sponsored randomized, controlled clinical studies, targeting combined enrollment of more than 1,100 patients.

H.P. Acthar Gel Pricing

The current "list price" per vial for the drug is $36,382, not the higher numbers which have appeared in various reports, and Mallinckrodt discounts this list price to both public and private payers. Mallinckrodt takes our responsibility as a pharmaceutical manufacturer very seriously, and our pledge on drug pricing and innovation describes our philosophy around responsible pricing.

H.P. Acthar Gel Dosage

H.P. Acthar Gel is an injectable formulation, and therefore physicians have flexibility in dosing in order to prescribe and administer the amount of drug they believe is needed (based on clinical data and their own experience) to effectively treat their patient's symptoms. This means that dosing may differ between the conditions it is used to treat and between individual patients.

There is no evidence – and Mallinckrodt has no reason to believe – that the amount of H.P. Acthar Gel prescribed to individual patients by their respective physicians is excessive. There may, however, be some confusion about the difference between dosages (USP units), and vials of H.P. Acthar Gel that could lead to misunderstanding about prescribing behavior by doctors. For reference, dosing information can be found in the FDA-approved prescribing information (label).

MNK-1411

MNK-1411 (formerly Synacthen® Depot) is simply *not* a "generic competitor to Acthar" – the two products are very different drugs. MNK-1411 is not approved by the FDA for any indications, and has never been commercialized in the United States. H.P. Acthar Gel is biologically derived and amongst its many components includes a 1-39 peptide chain so includes more than simply ACTH, while MNK-1411 is a synthetic 24-peptide chain. Importantly, the company believes the regulatory path for any corticotropin-type new drug

application would require FDA approval and, if successful, could take many years.

Reimbursement

Specific to reimbursement, coverage gains among commercial payers has resulted in the overall payer mix for H.P. Acthar Gel between private and public plans becoming – and staying – relatively stable, and Mallinckrodt is seeing volume growth across both publicly and privately insured patients.

Medicare patients represent a slightly higher percentage of overall patients simply because presentation of expanding data sets to healthcare practitioners over time has resulted in increased usage in aging patient populations, particularly in the rheumatology and pulmonology spaces, where Medicare coverage is more likely to be utilized. H.P. Acthar Gel is typically used episodically and acutely with patients, as opposed to a drug that is used regularly or chronically with patients. Additionally, these patients are often on concurrent treatments.

In the commercial reimbursement space, the majority of payers have an established pathway for the use of H.P. Acthar Gel in those patients for whom it is appropriately prescribed - those with conditions covered by the FDA-approved label and for whom the product's extensive existing data and clinical experience support H.P. Acthar Gel's use as a proven therapy. The prior-authorization and reimbursement processes used by commercial payers rely on these criteria.

Partners to Help Reach Patients

Mallinckrodt engages with a variety of partners in all parts of the industry value chain to ensure access for appropriate patients who are prescribed H.P. Acthar Gel. The company contracts with the majority of the largest Pharmacy Benefit Managers in the U.S., among them Express Scripts.

As is common practice for self-administered, injectable products that are not stocked at neighborhood pharmacies and require special climate-controlled handling, Mallinckrodt utilizes a network of independent specialty pharmacies to deliver H.P. Acthar Gel to patients who have been prescribed the medicine. Mallinckrodt has individual contracts with each of the independent specialty pharmacies in its network, of which Accredo, a specialty pharmacy owned and operated under the Express Scripts umbrella, is one. The pharmacies Mallinckrodt contracts with are selected based on a number of criteria, including their overall ability to fulfill prescriptions and provide product to patients in a timely manner.

To deliver H.P. Acthar Gel to its network of independent specialty pharmacies who then deliver the medicine to patient's homes, Mallinckrodt also contracts with Express Scripts' subsidiary CuraScript SD.

Mallinckrodt also has two other contracts with another separately owned Express Scripts subsidiary, United BioSource Corporation – one to manage order processing for the product, and another to conduct income or means testing for a program under which Mallinckrodt provides free product to low-income, uninsured or underinsured patients who qualify.

Utilization of all these services is a standard industry practice for most specialty pharmaceutical drugs, of which H.P. Acthar Gel is one.

Summary

Mallinckrodt strongly believes in the product's efficacy in its approved indications and will continue significant investment in H.P. Acthar Gel to ensure those patients who can benefit from the therapy have access to it.

About H.P. Acthar® Gel (repository corticotropin injection)

H.P. Acthar Gel is an injectable drug approved by the FDA for the treatment of 19 indications. Of these, today the majority of H.P. Acthar Gel use is in these indications:

- As an orphan monotherapy medication for the treatment of IS in infants and children under 2 years of age.
- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
- Treatment of acute exacerbations of multiple sclerosis in adults.
- Use during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus.
- Use during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis).

- Use as adjunct therapy for short-term administration in psoriatic arthritis; rheumatoid arthritis, juvenile rheumatoid arthritis and ankylosing spondylitis to tide patients over an acute episode or exacerbation.
- Treatment of symptomatic sarcoidosis.
- Treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis; iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis; anterior segment inflammation.

For more information about Acthar, please visit www.acthar.com. Please click to see full Prescribing Information and Medication Guide.

Important Safety Information

Contraindications

- Acthar should never be administered intravenously.
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of Acthar.
- Acthar is contraindicated where congenital infections are suspected in infants.
- Acthar is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origins.

Warnings and Precautions

- The adverse effects of Acthar are related primarily to its steroidogenic effects.
- Acthar may increase susceptibility to new infection or reactivation of latent infections.
- Suppression of the hypothalamic pituitary adrenal (HPA) axis may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Cushing's Syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms.
- Monitor patients for elevation of blood pressure, salt and water retention, and hypokalemia.
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and following discontinuation.
- Acthar can cause gastrointestinal (GI) bleeding and gastric ulcer with an increased risk for perforation with certain GI disorders. Monitor for signs of bleeding.
- Acthar may be associated with central nervous system (CNS) effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, depression, and psychosis. Existing conditions may be aggravated.
- Patients with comorbid disease may have that disease worsened. Caution should be used in patients with diabetes and myasthenia gravis.
- Prolonged use of Acthar may produce cataracts, glaucoma and secondary ocular infections.
- Acthar is immunogenic and prolonged use may increase the risk of hypersensitivity reactions.
- There is an enhanced effect in patients with hypothyroidism and those with cirrhosis of liver.
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients.
- Decrease in bone density may occur. Monitor during long-term therapy.
- Pregnancy Class C: Acthar has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Adverse Reactions

- Common adverse reactions include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain.
- Specific adverse reactions reported in IS clinical trials in infants and children under 2 years of age included: infection, hypertension, irritability, Cushingoid symptoms, constipation, diarrhea, vomiting, pyrexia, weight gain, increased appetite, decreased appetite, nasal congestion, acne, rash, and cardiac hypertrophy. Convulsions were also reported, but these may actually be occurring because some IS patients progress to other forms of seizures and IS sometimes mask other seizures, which become visible once the clinical spasms from IS resolve.

Please see full Prescribing Information here for additional Important Safety Information.

ABOUT MALLINCKRODT

Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; and analgesics and hemostasis products. The company's core strengths include the acquisition and management of highly regulated raw materials and specialized chemistry, formulation and manufacturing capabilities. The company's Specialty Brands segment includes branded medicines and its Specialty Generics segment includes specialty generic drugs, active pharmaceutical ingredients and external manufacturing. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission (SEC) disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

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EXHIBIT D

FACTS ABOUT H.P. ACTHAR GEL®

Updated June 29, 2018

H.P. Acthar® Gel Value to Patients

Our mission at Mallinckrodt is Managing Complexity. Improving Lives. Our employees live this mission every day, and we're focused on providing safe, effective treatments that make a difference in the lives of patients, especially those with severe and critical conditions.

A number of media outlets and other external parties have made misleading and inaccurate allegations about H.P. Acthar Gel (repository corticotropin injection) and Mallinckrodt. It is important to set the record straight.

Here are key facts:

- H.P. Acthar Gel is U.S. Food and Drug Administration (FDA)-approved for 19 indications, including for the treatment of Infantile Spasms, following a full label review by the Agency in 2010.
- The price of H.P. Acthar Gel today is $38,892, before discounts provided to payers. Since acquiring the drug in late 2014, Mallinckrodt has only made modest price adjustments in the mid-single digit percentage range.
- In contrast to the drug's prior owner Mallinckrodt has invested nearly $400 million into H.P. Acthar Gel, including investment into health economic and outcomes research and well-controlled clinical trials. Information on our total investment in H.P. Acthar Gel is publicly available on our website.
- Synacthen® (tetracosactide) is not H.P. Acthar Gel, nor is it an approved substitute for H.P. Acthar Gel in any of its indications in the U.S. Once we acquired the prior owner of Synacthen, we began developing the drug and in 2016, prior to the U.S. Federal Trade Commission (FTC) settlement, initiated clinical trials investigating use of the compound in Duchenne Muscular Dystrophy.
- Mallinckrodt strongly disagrees with the allegations contained in the City of Rockford, Illinois complaint.
- Mallinckrodt adheres to all regulations, guidance and codes related to interactions with healthcare providers.

Please see additional facts below along with other resources.

Patient Videos **Acthar.com** **Acthar Fact Sheet**

Clinical Presentation May 2017

June 29, 2018

The Facts About H.P. Acthar Gel

H.P. Acthar Gel (repository corticotropin injection) is for many frequently, very sick patients, a life-changing drug. We are proud of H.P. Acthar Gel and the important investment we are making in it, and we are gratified that we can positively impact patients' lives through this drug.

H.P. Acthar Gel is FDA-Approved for 19 Indications

While H.P. Acthar Gel has been used to treat patients for more than 50 years, its label was reviewed by the FDA in 2010, at which time the FDA determined there was sufficient scientific and clinical evidence to support its use in the 19 various indications1 contained in the current H.P. Acthar Gel label.

One of these indications is for use of **H.P. Acthar Gel in the treatment of Infantile Spasms (IS)2,** for which it is considered the gold-standard for treatment. Two randomized clinical trials were submitted in support of FDA approval of the drug and its effectiveness as a treatment for IS, one of which compared H.P. Acthar Gel to prednisone. In that trial 86.7% of patients had a positive response to H.P. Acthar Gel vs. 28.6% that responded to prednisone. Patients who responded in the pivotal study treated with a two-week course of H.P. Acthar Gel therapy experienced complete suppression of the two key measures of disease – spasms and hypsarrhythmia. The IS clinical trial results appear in Section 14 of the full prescribing information for the drug.

Aside from treatment of IS, H.P. Acthar Gel is often prescribed by doctors predominantly as a later-line treatment to a small subset of patients suffering from various devastating diseases for whom other approved FDA treatment options have failed.

The Price of H.P. Acthar Gel

In 2007, H.P. Acthar Gel's previous owner was near bankruptcy and raised the price of the drug substantially in order to keep the drug on the market and to ensure the long-term supply of the drug for treatment of children afflicted with infantile spasms and other small groups of patients suffering from complex, devastating diseases. They did this only after extensive consultation with the FDA.[3]

Today the price per vial of H.P. Acthar Gel is $38,892. Since acquiring H.P. Acthar Gel, Mallinckrodt has only made modest price adjustments in the mid-single digit percentage range. Additionally, Mallinckrodt provides discounts to this list price to payers, which the prior owner generally did not offer. We would encourage you to review Mallinckrodt's pledge on drug pricing and innovation, which we take very seriously.

NEW: Availability of H.P. Acthar Gel for Infantile Spasms Patients

- Mallinckrodt is committed to ensuring that any infant under the age of 2 suffering from infantile spasms (IS) who is prescribed H.P. Acthar® Gel receives treatment.[4]

- H.P. Acthar Gel samples are provided at no charge to physicians so they can provide the drug immediately upon diagnosis and assess the patient's clinical response to Acthar.
- All IS patient prescriptions received at the Acthar Hub are serviced urgently and with the utmost care knowing that a baby's well-being is at stake.
- A dedicated Acthar Hub Case Manager begins working immediately with the local Access and Reimbursement Manager to obtain insurance coverage and put the caregivers in touch with the Specialty Pharmacy to schedule expedited delivery.
- Mallinckrodt has a commercial copay assistance program to help offset out-of-pocket costs for eligible IS patients with no government insurance. The program offers a $0 co-pay for eligible patients.
    - Eligibility is established when the IS patient is a permanent U.S. resident, has a legal representative who is at least 18 years old, has been prescribed Acthar for this approved indication, and is commercially or privately insured.
    - The $0 co-pay program is not available to people insured by a federal or state healthcare plan or where prohibited by law.
- For those cases where the commercial or public insurance plan will not approve coverage for Acthar or the baby does not have insurance coverage – or for Medicaid patients whose families cannot afford the out-of-pocket costs – Mallinckrodt may provide Acthar at no cost to eligible patients through the Acthar Patient Assistance Program.
- Mallinckrodt also offers injection training services at no cost to the patient caregiver(s). A trained nurse will come to the best location (at the hospital, in the home, etc.) for the caregiver(s) and instruct them how to administer Acthar.

In short, Mallinckrodt invests significant resources to provide Acthar to babies quickly and with the utmost urgency. There is an entire support team that passionately and personally ushers each baby's prescription through the process to ensure no delays.

Mallinckrodt's Investment in H.P. Acthar Gel

Since acquiring H.P. Acthar Gel in 2014, Mallinckrodt has invested nearly $400 million into the drug, specifically: building on substantial clinical experience as well as previously completed and largely independent clinical case series and smaller trials; modernizing manufacturing; expanding medical affairs and research activities; and initiating six well-designed, company-sponsored randomized, controlled clinical studies, targeting combined enrollment of nearly 1,100 patients.3

Significant Clinical Evidence Supports the Efficacy of H.P. Acthar Gel

There is significant clinical evidence to support the effectiveness of H.P. Acthar Gel. This evidence is the result of company-sponsored controlled clinical trials, investigator-initiated research conducted in top hospitals and medical centers by some of the country's preeminent physicians, and health economic and outcomes research data. Equally important, there are decades of clinical experience that doctors have with the product as a proven therapy for appropriate patients.

As an FDA-approved drug, H.P. Acthar Gel is deemed safe and effective for its labeled indications by the agency. Since acquiring H.P. Acthar Gel, Mallinckrodt has, though, continued to conduct post-approval clinical studies in a number of key indications. Along with the wealth of clinical experience gained over the decades with this drug, this data will assist physicians in the use of H.P. Acthar Gel in the most appropriate patient populations.

NEW: Mallinckrodt recently published preliminary interim results of its Rheumatoid Arthritis Phase 4 Clinical Study for H.P. Acthar Gel. Details can be found here. The company also reported it achieved and exceeded enrollment for the trial.

NEW: Physician Payments/Travel Expense Reimbursement:

In the period of 2013-2016, of all healthcare practitioners prescribing H.P. Acthar Gel to whom Mallinckrodt or the prior owner made payments, **more than 95% received only modest meals or nominally priced clinical reprints** – well within regulations and guidelines. For the remaining ~5%, the vast majority were engaged for peer-to-peer speaking engagements, with a small fraction involved in other consulting services for the company, such as speaking to employees or investors and participation in expert Physician Advisory Boards – again, all within regulations and guidelines. It is our belief that many physicians prefer peer-to-peer presentations and dialogue over other methods of learning about the value a product may bring to appropriate patients they are treating. The physicians who present to their peers must take time away from their practice and frequently travel to other cities – incurring normal, but sometimes substantial travel expenses. Any payments reported include reimbursement for these expenses.

Mallinckrodt designs our policies to be consistent with applicable legal and regulatory requirements, the PhRMA Code, and industry best practices. We have instituted controls and strict guidelines regarding the selection and training of speakers; the conduct of such programs, including requirements related to the individuals that may attend such programs; and guidelines to ensure that the venues selected for such programs are appropriate and conducive to the educational focus of these programs, and payments are based on fair market value.

NEW: Adverse Events:

As an FDA-approved drug, H.P. Acthar Gel is deemed safe and effective for its labeled indications by the agency.

Mallinckrodt annually provides the FDA with data about adverse events related to its marketed products. As we approach our yearly filing, we are pleased to report that the positive benefit-risk of H.P. Acthar Gel has remained unchanged across all marketed indications and is consistent with previous years. To derive meaningful conclusions of this topic, adverse event reports for H.P. Acthar Gel need to be considered within the appropriate context.

H.P. Acthar Gel is typically prescribed to patients with very serious medical conditions, often as a third or fourth line of treatment when other treatments have failed. It is well known that many of these patients suffer from diseases in which co-morbidities are high, and often they are on other medications that may be contributing factors. The frequency of adverse event reports also does not necessarily correlate to an increase in the actual prevalence or relative severity of any particular side effect or event. Each event is reported and counted whether it relates to a relatively minor event such as a headache or a more serious event such as anaphylaxis.

Furthermore, the FDA itself cautions on its website that reporting of a side effect or adverse event occurring while taking a drug doesn't establish a causal relationship between the adverse event and the medicine.

Over the past years, the number of patients using H.P. Acthar Gel has increased significantly. Critically, however, company-generated H.P. Acthar Gel data on adverse events over the last four calendar years indicates that the number of serious adverse events as a proportion of the number of H.P. Acthar Gel prescriptions (measured by vials sold) has remained very low and consistent with the FDA's independent analysis.

NEW: H.P. Acthar Gel Advisory Committee Results

Regarding your questions on this topic, these are the facts: On May 11, 2010, a meeting of the FDA's Peripheral and Central Nervous System Drugs Division held an Advisory Committee Meeting (AdCom) to review/discuss the data Questcor was submitting/had submitted in support of use of H.P. Acthar Gel in treatment of patients with Infantile Spasms. The Committee voted 22 to 1 that H.P. Acthar Gel was an effective treatment for patients with IS and voted 20 to 1 the drug was safe in the intended patient population at an effective dosing regimen, inclusive of a Risk Evaluation and Mitigation Strategy (REMS). The REMS was a part of the agency's eventual approval of the drug for this indication (along with the reaffirmation of 18 others) in 2010. Two years later, the FDA removed the REMS requirement based on H.P. Acthar Gel's demonstrated safety in the market in IS patients.

The Facts about the Rockford Lawsuit

Mallinckrodt strongly believes that none of the company actions outlined in the plaintiff's complaint constitute a violation of any law and, therefore, believes that the complaint should be dismissed in its entirety. We will vigorously defend the company in this matter.

Treating physicians prescribe what they believe is best for their patients and the doctor(s) in Rockford, Illinois chose to prescribe H.P. Acthar Gel. The medical community is well aware that there are other treatment options for IS such as high dose steroids.

Synacthen, H.P. Acthar Gel and the FTC Settlement

Synacthen **is not a generic competitor** to H.P. Acthar Gel. While the two drugs may share mechanistic effects through the ACTH component, H.P. Acthar Gel is much more. H.P. Acthar Gel is a biologically derived corticotropin drug – not a steroid – and amongst its many components includes a 1-39 peptide chain, meaning it includes more than simply ACTH. Synacthen is a synthetic ACTH 24-peptide chain. The two products are very different drugs.

Mallinckrodt did not pursue commercialization of Synacthen for IS, as the barriers to completion were, in our view, virtually impossible to overcome.

- Synacthen has never been approved by the FDA for use in the U.S. for any indication and it is not an alternative treatment for IS in the U.S.
- In all the time that Synacthen has been commercially available in select foreign countries, it has never been commercialized in the U.S. and no owner of Synacthen (including the owner prior to Questcor) ever undertook U.S. development of the drug in IS or any other indication.
- Even in Canada, where Synacthen is approved and used in certain indications, it is not approved for use in IS patients. In fact, in Canada, the label contains a warning against use in infants or children under 3 years old due to the product containing benzyl alcohol.

Mallinckrodt is developing the drug (MNK-1411) in an indication where there is both high unmet medical need and, if successful, potential for greatest impact for patients – Duchenne Muscular Dystrophy.

Thank you for taking the time to read this important information.

1The FDA conducted a thorough review of the label for H.P. Acthar Gel in 2010.
2Because symptoms of IS can be subtle and are generally not widely recognized, Mallinckrodt invests resources to support education of the medical and patient community to ensure IS babies are getting diagnosed promptly. We also invest in ongoing clinical research to further understand the disease and since treating infantile spasms is so urgent once diagnosed Mallinckrodt has established an entire support team to usher each baby's prescription through the coverage process to ensure quick access to the product.
[3]Please see the Questcor's 10-K filing for 2007. Additionally, Questcor issued many new shares the year before, presumably to raise capital. Moreover, articles have appeared, including one in Investor's Business Daily in November of 2013 in which the former CEO of Questcor publicly discussed the company's challenges to stay afloat during this time period.
[4]Patients who withdrew from the process on their own would be exceptions to this statement.
[5]The six ongoing clinical trials are referenced below. Each link takes you to the announcement of the first patient enrolled in the clinical trial. Within each press release, in the "About the Trial" section, you will see a link to further details about the study that can be found on www.clinicaltrials.gov. These important investments will build upon the existing body of clinical evidence to support the effectiveness of H.P. Acthar Gel.

• Phase 2B trial in Amyotrophic Lateral Sclerosis
• Phase 4 trial in Pulmonary Sarcoidosis
• Phase 4 trial in Multiple Sclerosis Relapse
• Phase 4 trial in Lupus
• Phase 4 trial in Rheumatoid Arthritis
• Phase 4 trial in Focal Segmental Glomerulosclerosis (Nephrotic Syndrome)

About H.P. Acthar Gel (repository corticotropin injection)

INDICATIONS

H.P. Acthar Gel is an injectable drug approved by the FDA for the treatment of 19 indications. Of these, today the majority of Acthar use is in these indications:

- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus
- Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- The treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis)
- The treatment of symptomatic sarcoidosis
- Adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)
- Treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation

IMPORTANT SAFETY INFORMATION

Contraindications

- Acthar should never be administered intravenously
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of Acthar
- Acthar is contraindicated where congenital infections are suspected in infants
- Acthar is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origins

Warnings and Precautions

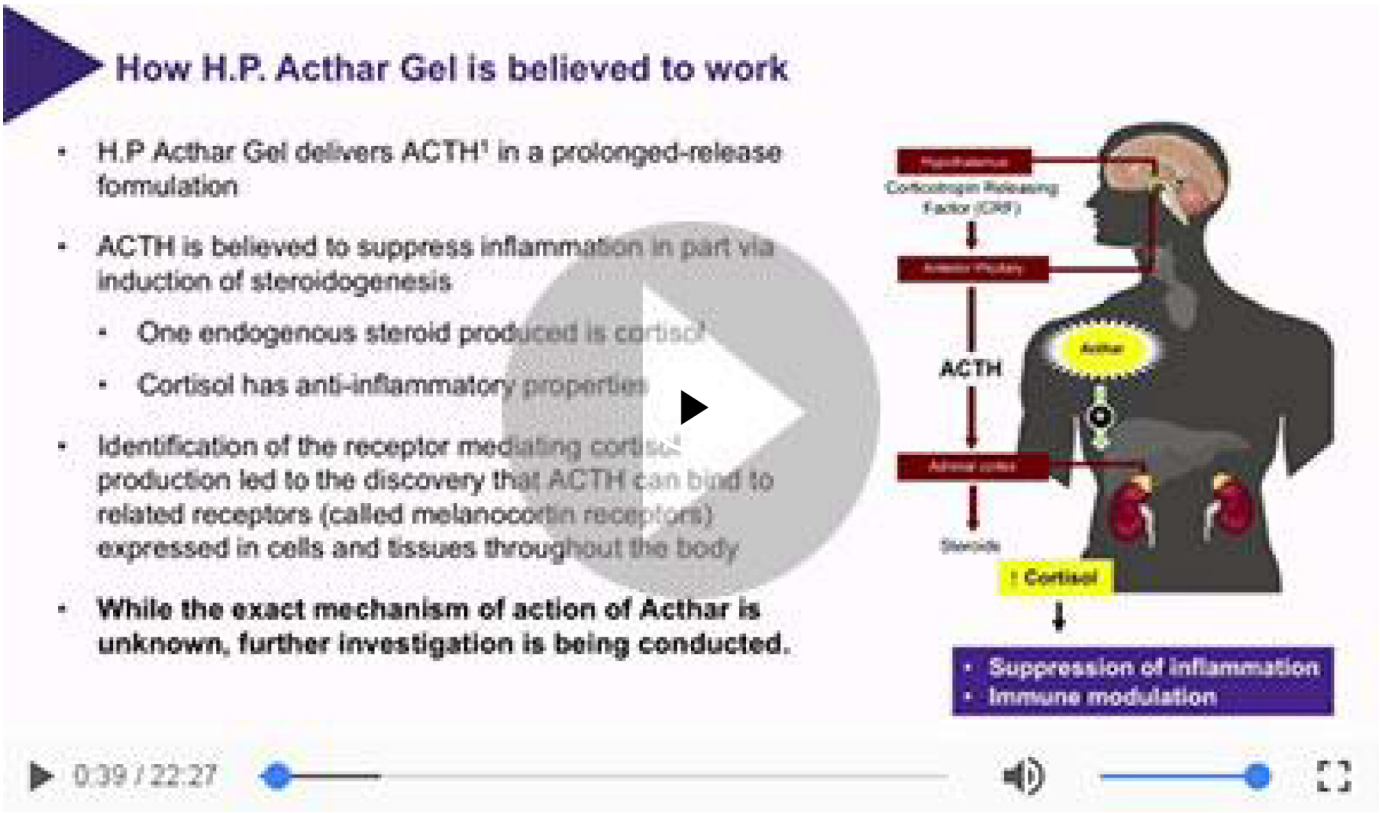
- The adverse effects of Acthar are related primarily to its steroidogenic effects
- Acthar may increase susceptibility to new infection or reactivation of latent infections
- Suppression of the hypothalamic-pituitary-axis (HPA) may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by tapering of the dose when discontinuing treatment. During recovery of the adrenal gland patients should be protected from the stress (e.g. trauma or surgery) by the use of corticosteroids. Monitor patients for effects of HPA suppression after stopping treatment
- Cushing's syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Blood pressure, sodium and potassium levels may need to be monitored
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy
- Acthar can cause GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Monitor for signs of bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression, and psychosis. Existing conditions may be aggravated
- Patients with comorbid disease may have that disease worsened. Caution should be used when prescribing Acthar in patients with diabetes and myasthenia gravis
- Prolonged use of Acthar may produce cataracts, glaucoma and secondary ocular infections. Monitor for signs and symptoms
- Acthar is immunogenic and prolonged administration of Acthar may increase the risk of hypersensitivity reactions. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH activity
- There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients
- Decrease in bone density may occur. Bone density should be monitored for patients on long-term therapy
- Pregnancy Class C: Acthar has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

Adverse Reactions

- Common adverse reactions for Acthar are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain
- Specific adverse reactions reported in IS clinical trials in infants and children under 2 years of age included: infection, hypertension, irritability, Cushingoid symptoms, constipation, diarrhea, vomiting, pyrexia, weight gain, increased appetite, decreased appetite, nasal congestion, acne, rash,

and cardiac hypertrophy. Convulsions were also reported, but these may actually be occurring because some IS patients progress to other forms of seizures and IS sometimes mask other seizures, which become visible once the clinical spasms from IS resolve

Other adverse events reported are included in the full Prescribing Information.
Please see full Prescribing Information available at Acthar.com.



Patient Videos

Each of the stories below provide a view of patients who are taking action to treat their disease or condition with Acthar.

Bella – infantile spasms
Christine – multiple sclerosis
Cynthia – dermatomyositis
Ella – infantile spasms
Daryl – multiple sclerosis
Gloria – rheumatoid arthritis
Kimberly – multiple sclerosis
Maby – multiple sclerosis
Tottie – polymyositis
Yosafa – multiple sclerosis
Zachary – infantile spasms